EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DUANE PRIDDY, PH.D.

I. QUALIFICATIONS

In 1971 I received a Ph.D. in Organic Chemistry from Michigan State University. I joined Dow Plastics in 1972. I retired from Dow Plastics in 2001 as a Principal Scientist. During my years at Dow, I led a team of Plastic Scientists that worked together to understand the science of plastic degradation in order to help Dow develop improved antioxidant stabilizer formulations for Dow's plastic products. Our goal was to understand, not only the mechanism of degradation of plastics, but also the mechanism of degradation of antioxidants causing them to become depleted from the plastic. In 1995 I published a peer reviewed scientific paper entitled "Permanence of Polymer Stabilizers in Hostile Environments," which addresses the topic of the loss of stabilizers from plastics allowing the plastic to rapidly degrade.[1] I also helped Dow develop several medical grade plastic formulations. Following my retirement from Dow in 2001, I started Plastic Failure Labs. Over the past decade I have served as an expert witness in over 150 litigations involving the failure of plastic products, including medical devices. I have published many articles and scientific publications involving the science of plastics, how they fail, and how to select the right plastic for specific applications.

Because of my many contributions to the development of a better understanding of the science of degradation of plastics, I have received many awards and honors including: Lifetime Achievement Award (Dow), Fellow (Polymeric Materials Div. of the American Chemical Society), and Fellow (Society of Plastic Engineers). I have worked as a plastics consultant for the following medical supply companies: Spectranetics, StatLabs, Baxa, Terumo, and American Medical Systems performing failure analysis, material selection, and product life predictions. A full and accurate copy of my Curriculum Vitae is attached as Exhibit A.

[1] "Permanence of polymer stabilizers in hostile environments," Journal of Applied Polymer Science (1994), 54(11), 1605-12.

II. EXECUTIVE SUMMARY

I have been asked to address the chemical stability of the polypropylene (PP) polymer used by Ethicon, Inc., Gynecare, and Johnson & Johnson (collectively referred to as Ethicon) associated with the manufacture of Ethicon's mesh products designed to treat Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP). When I refer to PP in this Report, I am referring to the PP resin used by Ethicon in both their SUI and POP devices. All of my opinions in this Report are offered to a reasonable degree of professional certainty within my field.

There are thousands of different plastic products and grades on the market. Choosing the right plastic for any given application is critical, especially for medical implants where failure can be life-threatening. As a Plastic Scientist, I have been trained and have devoted my 40+ year career developing a scientific understanding of how different plastics perform under different use conditions, including for medical applications. I have also developed an understanding of the degradation science of different plastics, their service life, and how they eventually fail. Based on my education, training and experience, my opinion in this case is that Ethicon should not have used PP in its SUI and POP devices because of the unstable chemical nature of this material. The testing and analysis that I have done as part of my work confirms my opinions based on the scientific literature and my experience. Furthermore, the testing that I have done in this case is the same testing and analysis that I have done throughout my career, including as part of my work for Dow Plastics and is accepted by my peers and industry. I would have performed this same analysis and testing for Ethicon at any time during the marketing of their SUI and POP PP devices if they had asked me to do so and would have given them the same opinions I set forth in this report.

Because of the reactive tertiary carbon—hydrogen bonds along the PP polymer chains—PP is not inert[2] and must be heavily stabilized with the addition of antioxidants in order to simply survive fabrication into parts. The addition of antioxidants to PP allows it to be fabricated into parts and prolongs its useful life. However, it is not possible or feasible to stabilize PP to make it last for decades in an application where it:

1) has high surface area exposed to oxygenated medium;
2) is under stress;
3) is in a constant warm environment; and
4) is exposed to fluids containing organics capable of extracting antioxidant stabilizers from the exposed surface.

These basic Polymer Science principles are accepted in my field of expertise. Accordingly, it is my opinion that Ethicon should not have used PP as a material in permanent medical implants.

As part of my work in this case, I have performed ASTM D3895 "Oxidative Induction Time" (OIT) testing. ASTM 3895 OIT is a standard test method that outlines a procedure for determining the resistance of a material to oxidation using differential scanning calorimetry (DSC). This testing is

[2] *See* E. Rene de la Rie. *Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field*. STUDIES IN CONSERVATION. 33: 9-22 (1988); Clavé, A. et al. *Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants.* Int. Urogynecol. J. 21:261-270 (2010); Costello, C.R. et al. *Materials Characterization of Explanted Polypropylene Hernia Meshes.* J. Biomed Mater. Res. Part B: Appl. Biomaterials. 83B: 44-49 (2007).

an accelerated thermal aging test which is commonly used to evaluate the oxidative resistance of polyolefin resins like PP.[3,4] OIT measures a material's resistance to oxidative decomposition. As part of my work in this case, OIT was used to compare the relative thermal oxidative stability of 10 different Ethicon mesh samples in order to determine the lot to lot variability of the oxidative stability of the meshes. As part of my work in this case, I followed a standardized protocol listed in ASTM D3895. I did not deviate from the protocol listed in this testing procedure. I examined the data to also determine the point at which the surface of the mesh shows evidence of incipient oxidation. This measures incipient surface oxidation time (ISOT), which is measuring surface oxidation. Measuring surface oxidation is important because how and when oxidation affects the surface of PP is the beginning of the embrittlement process, which will affect the physical structure of the PP.

Over 150% variance was found between the 10 exemplar samples. This variance is significant because it indicates that there are wide differences among the oxidative stability of the ten (10) tested samples. These differences between different samples indicates that the oxidation process will be unpredictable—meaning that the material in different lots of Ethicon SUI and POP PP devices will degrade at varying rates. Thus the products are not expected to behave consistently across product lines and within product lines.

The data was also used to evaluate the performance of the antioxidant stabilizer in the Ethicon mesh samples and to predict the approximate time to oxidative degradation of the meshes following the Q10 protocol[5] as described in ASTM F1980 accelerated aging testing methodology. The estimated time for depletion of the antioxidants to measure incipient surface oxidative degradation of the meshes (under best case scenario conditions; i.e., no stress and no loss by extraction) is only a few months in some of the mesh samples. This result provides additional support for my opinion in this case that PP should not be used as a permanently implantable medical material due to its unstable chemical nature; that the oxidative process begins quickly; and that the oxidative process is accelerated in an environment of stress, heat and oxidative agents. This is well-documented in the scientific literature and it is commonly understood in my field. There is nothing unique about the Ethicon PP that changes these fundamental principles of polymer science.

Because the degradation science of PP has been well known for over 40 years,[6] and the availability of accelerated laboratory aging technology allowing rapid assessment of the rate of material degradation,[7] it is clear that Ethicon meshes manufactured using PP cannot survive long

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[3] Antioxidant Depletion and OIT Values of High Impact PP Strands"; Chinese Journal of Polymer Science , 27(3), 435−445(2009).

[4] "Accelerated testing method for evaluating polyolefin stability", ASTM special technical Publication: 1081", edited by Koerner, R.M., ASTM, page 57 (1990).

[5] "Shelf-Life Prediction for Radiation-Sterilized Plastic Devices," Medical Device Diagnostics,12(1):124–129 (1990); "How to Plan an Accelerated Life Test—Some Practical Guidelines", 10, Milwaukee, WI, American Society for Quality Control, 1985; "Shelf-Life Prediction of Radiation Sterilized Medical Devices," Society of Plastics Engineers ANTEC Technical Papers, 33, (1987); "Using the Arrhenius Equation and Rate Expressions to Predict the Long-Term Behavior of Geosynthetic Polymers," Geosynthetics, (1993); "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM; Woo L, and Cheung W, "Importance of Physical Aging on Medical Device Design," Society of Plastics Engineers ANTEC Technical Papers, 34 (1988); http://www.met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing.php .

[6] "The Deterioration of PP by Oxidative Degradation"; Polymer Engineering & Science, 152 (1965).

[7] "Shelf-Life Prediction for Radiation-Sterilized Plastic Devices," Medical Device Diagnostics,12(1):124–129 (1990); "How to Plan an Accelerated Life Test—Some Practical Guidelines", 10, Milwaukee, WI, American Society

term use as a reinforcing medical implant. Ethicon knew, or should have known; that this process of degradation affects the plastic's integrity from the beginning and can be predicted. PP's chemical nature and resulting instability also means that the Ethicon PP may degrade more rapidly based on the environment that it is in.

III. EXPLANATION OF PLASTIC STRENGTH

The longer the polymer chains, the greater the number of polymer chain entanglements, and the stronger the plastic. The general rule for plastics is that there should be at least an average of ten entanglements of each polymer chain with the other polymer chains for the plastic to have good strength. When plastics oxidize, the chains are broken and become shorter resulting in fewer entanglements and eventually the normally strong/ductile plastic becomes brittle like glass. This oxidation process starts before implant, as PP is subject to degradation or weakening by oxidative agents, including those found in the human body.[8]

IV. BACKGROUND ON OXIDATION AND DEGRATION OF HYDROCARBON MATERIALS

Hundreds of billions of pounds of plastic materials are manufactured and used each year around the world. Plastics are inherently oxidizable because they are hydrocarbons; i.e., they contain hydrogen bonded to carbon. Oxygen in the air oxidizes hydrocarbon materials replacing the hydrogen with oxygen causing them to degrade.[9] This is true of all materials that contain hydrogen bonded to carbon including the food we eat and the medicines we take. This is why the food we buy at the store and the medicines we take all have expiration dates on them. Because of the fact that most plastics are inherently unstable and degrade by oxidation, antioxidant stabilizers are generally added to plastics during their manufacture. These antioxidants allow the plastic to be heated and fabricated into parts and also prolong the useful life of the plastic. However, eventually the antioxidant stabilizers are consumed, allowing the plastic to oxidize and degrade. Some plastics are less stable and oxidize and degrade much faster than other plastics; e.g., PP. PP is a cheap commodity plastic. Because of its poor oxidative stability, PP is generally used primarily to manufacture products that have a short service life.

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for Quality Control, 1985; "Shelf-Life Prediction of Radiation Sterilized Medical Devices," Society of Plastics Engineers ANTEC Technical Papers, 33, (1987); "Using the Arrhenius Equation and Rate Expressions to Predict the Long-Term Behavior of Geosynthetic Polymers," Geosynthetics, (1993); "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM; Woo L, and Cheung W, "Importance of Physical Aging on Medical Device Design," Society of Plastics Engineers ANTEC Technical Papers, 34 (1988); http://www.met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing.php .

[8] *See* E. Rene de la Rie. *Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field*. STUDIES IN CONSERVATION. 33: 9-22 (1988); Clavé, A. et al. *Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants.* Int. Urogynecol. J. 21:261-270 (2010); Costello, C.R. et al. *Materials Characterization of Explanted Polypropylene Hernia Meshes.* J. Biomed Mater. Res. Part B: Appl. Biomaterials. 83B: 44-49 (2007).

[9] "What is oxidation and how does it alter food products?", http://shelflifeadvice.com/faq/what-oxidation-and-how-does-it-alter-food-products

Basic principles of chemistry teach that hydrocarbons (chemicals that contain hydrogen bonded to carbon) are constantly degrading by oxidation (reaction with oxygen).[10] When a material containing hydrogen bonded to carbon (C---H) is exposed to air, the hydrogen becomes replaced with oxygen by a free radical process. The rate of the oxidation reaction is about 10 times faster when the hydrogen is bonded to a tertiary carbon (as in PP) compared to a secondary carbon (as in polyethylene). For example, this is why PP degrades (by oxidation) much faster than polyethylene.[11] Because of the poor oxidation resistance of PP, PP must be heavily stabilized with antioxidants in order for the material to survive fabrication into articles and for the fabricated articles to have a reasonable service life. As a plastic chemist, I am aware that additives in plastics can migrate and are extractible, that antioxidant stabilizers added to medical implants must be suitable for use in medical devices, and that the antioxidants cannot be toxic to adjacent tissue surrounding the implant.

Based on my education, training and experience, I would not recommend the use of PP mesh as an implantable medical device, especially if that device cannot be removed in its entirety if complications arise. Degradation does not stop and the chemical reactions continue to occur so long as any oxidizing agents, such as those present in the human body, are present.[12] This means the oxidative process does not stop in the body until all of the mesh is removed.

V. PLASTICS IN MEDICINE

A. General

Plastics, including PP, are extensively used in medicine. Examples include pill bottles, petri dishes and tubing. However, these applications are short term and are external to the body so failure is not generally life-threatening. When plastics are placed in the body, the environment in is very different than outside the body. For example, when plastics are placed in the body, they are exposed to organic liquids (e.g., blood and fatty oils called lipids, glycerides). These chemicals act to extract the antioxidant stabilizers (very small molecules) from the long polymer chains in the plastic. Implantation of plastic inside the body also places a mechanical load or stress on it. In response to the mechanical stress, the polymer chains start to disentangle from each other and the plastic becomes weaker over time, eventually becoming brittle. As an implanted material loses its strength and fails, it can be a safety issue which can lead to serious infection and the need for further surgery. The oxidative process itself results in changes to the material, which can lead to embrittlement and complete oxidation. As I also note above, these chemical reactions can also be problematic if the PP cannot be removed.

B. Plastic Implants

[10] "Aerobic hydrocarbon oxidation," https://www.boundless.com/microbiology/textbooks/boundless-microbiology-textbook/microbial-metabolism-5/alternatives-to-glycolysis-47/aerobic-hydrocarbon-oxidation-303-3442/
[11] Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).
[12] Anderson, J.M., et al. *Foreign Boyd Reaction to Biomaterials*. Semin. Immulon. 20(2): 86-100 (2008).

One of the success stories of implanted plastics is artificial joints.[13] Because artificial joints are under very high mechanical stress during use, in order to overcome the problem with polymer chain disentanglement, manufactures of artificial joints make the polymer chains extremely long to maximize the number of entanglements. The polymer chains are so entangled that when some disentanglement occurs, they will always have greater than the minimum of ten entanglements required for good strength. The plastic material of choice for artificial joints is called ultra-high molecular weight polyethylene or UHMWPE.

A big challenge with UHMWPE is that the polymer chains are so long and so entangled that the plastic is extremely difficult to mold into shapes, thereby necessitating the use of special molding techniques.[14] As mentioned previously, polyethylene does not contain tertiary carbon – hydrogen bonds so it is much more stable than PP. However, even though UHMWPE has ultra-long polymer chain length and has much greater oxidative stability than PP, it still eventually degrades by oxidation often forcing replacement of the artificial joints after several years of service.[15] This is well known to me in my work because I have worked with and tested these concepts throughout my professional career. The testing I have performed as part of my work in this case is the same testing that I have used throughout my career, including with medical devices, and this testing is widely accepted in my field.

VI. MESH

A. Loss of strength by Polymer Chain Disentanglement

PP is the plastic used in the Ethicon mesh/fabric.[16] The mesh/fabric consists of threads that are woven together. In order to be able to extrude the PP to make skinny thread, the PP chains cannot be extremely long like those in the UHMWPE used for artificial joints because it would be impossible to force the extremely long polymer chains through a small die-opening to make skinny thread. Since the polymer chains are short and PP is prone to oxidative degradation, exposure of the mesh to stress in the body can cause the mesh to fail. Since the rate of oxidation and antioxidant extraction is greatest on the surface of the mesh fibers, the surface rapidly degrades and becomes brittle.[17] This basic scientific principle is well known and has been understood for several decades. Therefore a Plastic Scientist with an understanding of the degradation science of plastics can predict that PP mesh implants can begin to oxidize and degrade after implantation.

B. Loss of Strength by Oxidation

The basic chemistry of the oxidation of PP is depicted below:

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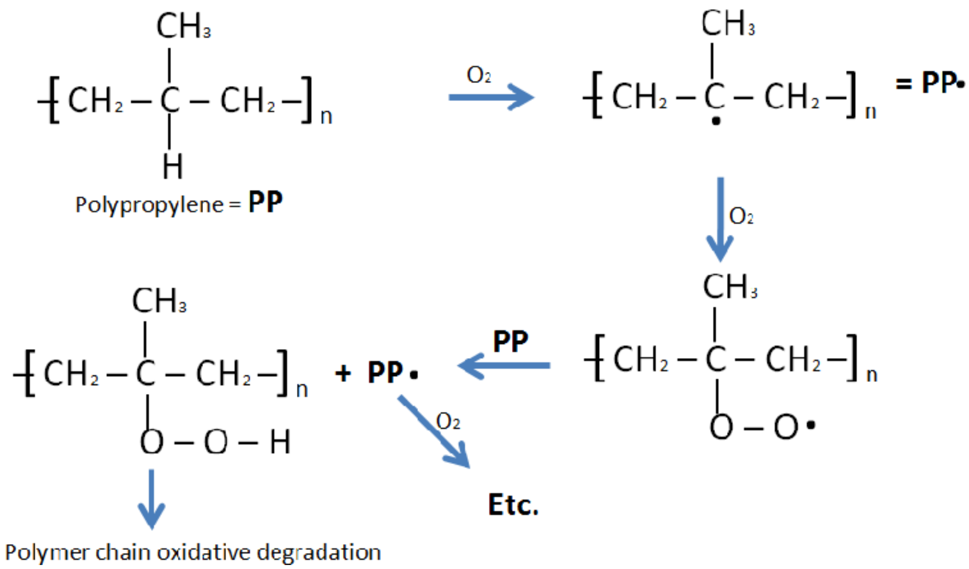
[13] "UHMWPE: Processing and Problems", www.uhmwpe.unito.it/2003/Allen.pdf; "UHMWPE Biomaterials handbook", https://books.google.com/books?hl=en&lr=&id=-50t0rdc0BgC&oi=fnd&pg=PP1&dq=molding+of+UHMWPE&ots=_KrkrTgRBX&sig=zX7hJUHNa12wqte-OMpxIeRA8Rw#v=onepage&q=molding%20of%20UHMWPE&f=false

[14] "UHMWPE: Processing and Problems", www.uhmwpe.unito.it/2003/Allen.pdf

[15] "UHMWPE Biomaterials handbook", https://books.google.com/books?hl=en&lr=&id=-50t0rdc0BgC&oi=fnd&pg=PP1&dq=molding+of+UHMWPE&ots=_KrkrTgRBX&sig=zX7hJUHNa12wqte-OMpxIeRA8Rw#v=onepage&q=molding%20of%20UHMWPE&f=false

[16] *See* Eth.Mesh.02268619 ("Prolene Resin Manufacturing Specifications").

[17] "Subcutaneous Implants of PP Filaments"; Journal of Biomedical Material Research, 10, 939 – 851 (1976).



Oxygen in the air abstracts the labile (reactive) tertiary hydrogen (H) atoms from the PP backbone to produce carbon free radicals. Carbon free radicals are highly reactive and rapidly react with oxygen to form peroxide radicals. Peroxide radicals are also highly reactive and react with other tertiary H atoms on PP to form more PP radicals and convert the peroxy radical to a hydroperoxide group which is unstable and decomposes to form a ketone causing the PP polymer chain to break into two shorter chains and to propagate a chain reaction. If PP is not stabilized with antioxidants, it will be so unstable that it would not even survive being heated up and fabricated to make a mesh, let alone survive implantation into a highly oxidizing environment inside the body. The only thing that allows Ethicon mesh to survive even short term implantation is the presence of antioxidants (e.g., Santanox R) which interfere with the oxidative chain reaction.

However, there are inherent problems with implanting an unstable plastic in the body and relying on antioxidants to prolong its life. The problems include: reliance upon small molecules which migrate from the surface of the mesh;[18] and the antioxidants are themselves degraded over time[19] becoming depleted from the PP. Once the antioxidants are extracted by body fluids and depleted from the surface of the mesh, surface embrittlement of the fibers ensues (Figure 1). Embrittlement of the PP occurs on the surface and leads to microcracking, which then stimulates crack initiation and crack propagation. If mechanical stress is also placed on the PP fibers, it will enhance the degradation effect and further lead to crack propagation, especially with a material that is under a constant mechanical stress. Embrittlement of the surface of the PP mesh fibers leads to a substantial decrease in the mechanical and physical properties of meshes. This is basic polymer chemistry that is well understood by Plastic Scientists and was known at the time that Ethicon began using PP in SUI and POP products.[20]

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[18] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[19] "Permanence of polymer stabilizers in hostile environments," Journal of Applied Polymer Science (1994), 54(11), 1605-12.
[20] "Characterization and Failure Analysis of Plastics," ASM International (2003), https://books.google.com/books?id=RJWiilJLdxYC&pg=PA17&lpg=PA17&dq=affect+of+polymer+molecular+wei

VII. SANTANOX R ANTIOXIDANT USED IN ETHICON MESH

The PP used in Ethicon mesh is stabilized using antioxidants (e.g., Santanox R).[21] Ethicon documentation reveals that there are additional additives added to the Prolene resin, including Calcium Stearate, Dilauralthiodipropionate (DLTDP), Procol LA-10, and CPC Pigment.[22] My testing in this case (gas chromatography – mass spectroscopy (GC-MS)) did not detect the presence of any of the additive other than Santanox R.

The chemical oxidation process of plastics and the stabilization chemistry of antioxidants like Santanox R are well understood (Scheme 1). Santanox R contains both hindered phenol and sulfur. Sulfur reacts with peroxides to convert them to alcohols. A problem is, as the Santanox R does its job, it is constantly being converted to a different chemical which is not an antioxidant. It is also known that Santanox R is depleted by migration into adjacent fluid.[23] Once depleted, the PP is completely unstabilized and is free to more rapidly oxidize and become brittle. Of course, the degradation process occurs first on the surface of the fibers because of the migration of the antioxidants from the surface, and the oxidizing environment is greatest on the fiber surface. This is why the scientific literature shows embrittlement of the surface layer on the fibers of explanted meshes (Figure 1).[24]

Scheme 1. The chemistry of PP oxidation stabilized with Santanox R.

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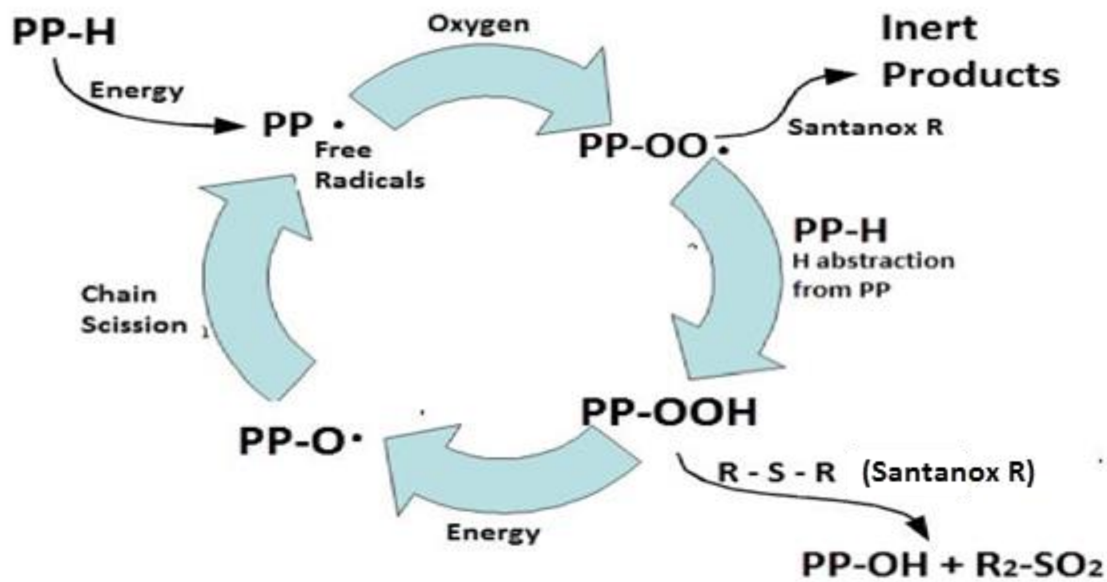
[21] *See* Eth.Mesh.02268619 ("Prolene Resin Manufacturing Specifications").

[22] Id.

[23] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).

[24] Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants"; Int Urogynecol Journal, 21, 261–270 (2010); Biodegradation of Surgical Polymers"; Journal of Material Science, 17, 1233 – 46 (1982); Materials Characterization of Explanted Polypropylene Hernia Meshes"; Journal of Biomechanical Materials Research, Part B: Applied Biomaterials, 83B: 44–49 (2007); Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients"; Journal Biomed Mater Res Part B: Applied Biomaterials 91B: 1 - 12, (2015); "In vivo Oxidative Degradation of Polypropylene Pelvic Mesh"; Biomaterials, 71, 131 – 141 (2015); "Materials characterization and histological analysis of explanted PP, PTFE, and PET hernia meshes from an individual patient"; Journal of Material Science: Material Medicine; 24, 1113 – 1122 (2013); Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward"; European Urology, 64, 525 – 529 (2013); Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes"; Hernia, 16, 251 – 258 (2012); "Pathological Findings of Transvaginal PPP Slings Explanted for Late Complications: Mesh is not Inert"; Conference paper presented in 2014; see https://www.researchgate.net/publication/273135551PathologicalFindingsofTransvaginalPolypropyleneSlingsexplantedforLateComplicationsMeshisNotInert; "Failure Analysis of Transvaginal Mesh Products a Biomaterials Perspective Using Materials Science Fundamentals"; Paper presented at 2014 AICHE conference; "Pathology of Explanted Transvaginal Meshes"; International Journal of Medical Health, 8(9), 510 – 513 (2014); "Physical Characteristics of Medical Textile Prostheses Designed for Hernia Repair: A Comprehensive Analysis of Select Commercial Devices"; Materials, 8(12), 8148-8168 (2015); Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).



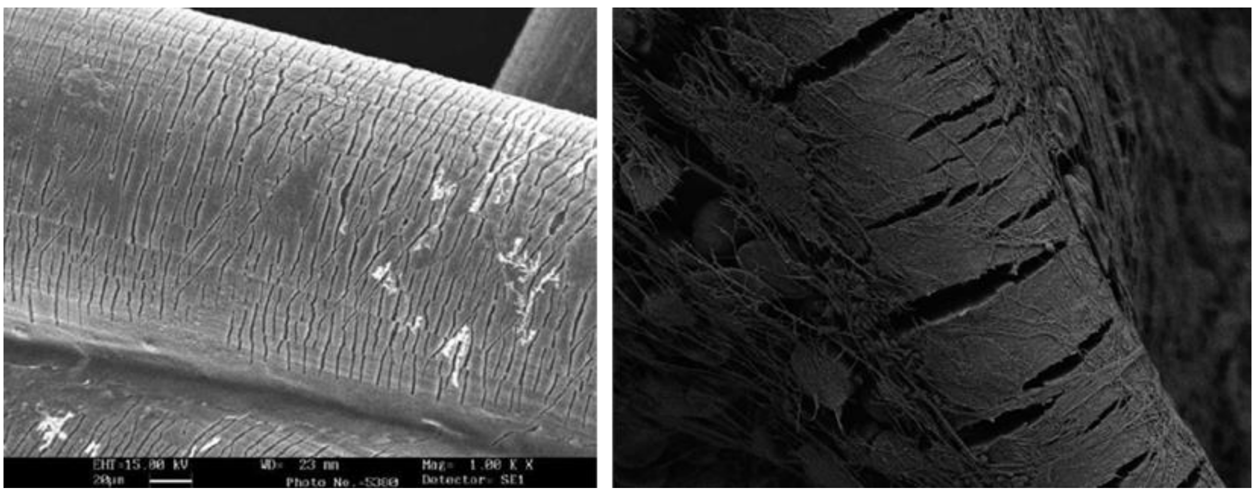


Figure 1. Scanning electron microscope (SEM) images of the surface of explanted meshes revealing severe surface degradation of the mesh fibers.[25]

VIII. SUMMARY AND CONCLUSIONS ON PP DEGRADATION SCIENCE

To summarize, from a plastic science perspective, I would not advise a medical device company to use PP for the permanently implantable mesh application because:

1) In order to fabricate a mesh, the PP polymer chains must be short;

2) PP mesh will rapidly lose its strength as the polymer chains disentangle when the mesh is placed under mechanical stress;

[25] “Post implantation Alterations of PP in the Human,” Journal of Urology, 188, 27 – 32 (2012).

3) The PP is inherently oxidatively unstable compared with other plastics (because of the tertiary bonded hydrogen) forcing the addition of high levels of antioxidant stabilizers to be added to the PP to allow it to be stable enough to be fabricated into mesh without material degradation.

4) The antioxidants are depleted by migration from the mesh and by oxidation as they do their job to protect the PP against degradation.

5) Oxygenated liquids (e.g., blood, lipids and glycerides) present in body tissue extract antioxidants from the surface of the PP allowing rapid degradation and embrittlement of the surface of the mesh fibers.

IX. REVIEW OF RESEARCH ON PP MESH IMPLANTS

Polymers have been implanted in the body for several decades. All polymers degrade in the body and the basic science of degradation of different polymers in the body is known.[26] However, the rate at which a polymer degrades depends on the polymer's structure. For example, the rate of the oxidation reaction is about ten times faster when the hydrogen is bonded to a tertiary carbon (as is the case with PP) compared to a secondary carbon (as is the case with polyethylene). This is why PP degrades (by oxidation) much faster than other polymers, such as polyethylene.[27] PP meshes have also been used and studied for decades as well. Researchers at the University of Cincinnati College of Medicine found that unstabilized PP filaments begin to degrade after only a few days of implantation and that the mechanism of in vivo degradation is auto-oxidation similar to the degradation process that occurs during exposure of PP to air.[28] They found that the addition of appropriate antioxidants to the PP are required in order to stabilize the PP and increase the induction time for the start of the oxidative degradation process.

Professor Jimmy Mays at the University of Tennessee, recently (December 2015) published a paper in a peer reviewed journal (Biomaterials).[29] Professor Mays' research group showed that PP mesh implanted in the body undergoes rapid oxidative degradation leading to loss of filament strength and cracking. They conclude: "The overall degradation process of PP pelvic meshes may be summarized as follows. The implant causes increased activity by oxidative enzymes in the vicinity of the implant. This leads to an oxidative degradation process that is evidenced by appearance of hydroxyl and then carbonyl groups in the polypropylene, as observed by infrared spectra. There is accompanying degradation of the polypropylene molecular weight, and this process may be delayed, but not prevented, by the presence of antioxidants in the polypropylene. Antioxidants are preferentially consumed by the oxidizing species and finally the concentration falls below a level required to protect the polymer and oxidative degradation occurs. This degradation is accompanied by a decrease in mechanical properties (embrittlement, loss of mass, decreased melting temperature,

[26]"Handbook of Polymer Applications in Medicine and Medical Devices, 1st Edition; PDL Handbook Series. Editors: Modjarrad & Ebnesajjad , 386 pages, (2013); "Biomaterials, Medical Devices, and Combination Products: Biocompatibility Testing and Safety Assessment"; Taylor & Francis, CRC Press, 561 pages, 2015; Biodegradation of Surgical Polymers"; Journal of Material Science, 17, 1233 – 46 (1982); Comparison of PP and PET meshes for abdominal wall hernia repair: A chemical and morphological study"; Hernia, 9, 51–55 (2005).
[27] Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).
[28] "Subcutaneous Implants of PP Filaments"; Journal of Biomedical Material Research, 10, 939 – 851 (1976).
[29]In Vivo Oxidative Degradation of Polypropylene Pelvic Mesh. Biomaterials (2015) Volume 73: 131-141.

reduced compliance) of the polypropylene. In particular, the surface and amorphous regions of the polypropylene are selectively degraded, resulting initially in cracks and, on longer exposure, fragmentation of the implant."[30] This is consistent with my opinion in this case.

X. ETHICON DEGRADATION RATE USING ACCELERATED LAB TESTING

Polymers are required to have a service life appropriate for their intended use. The term "service life" has a wide range of expectations. Some examples include exposure to high temperatures and aggressive solvents in automotive under-the-hood applications, long term service in elevated temperature environments such as electronic circuit boards, the ability of plastic pipes to withstand high pressure for decades while being exposed to chlorinated water, and the ability to withstand weather extremes in residential siding. In all of these examples, design engineers require information on polymer properties as a function of service time in order to create viable parts that meet the service expectation. In medical applications selecting the right material to manufacture implants is even more critical because failure can be life-threatening. Responsible medical device companies use accelerated aging testing to predict the estimated time to failure of the product. It can create a so-called red flag; if accelerated lab testing predicts a failure time that is shorter than the amount of time that the medical device can be present in the body, a responsible manufacturer should conduct additional, lengthier tests to confirm that the material is (or is not) stable enough to remain in the body for the length of time required. Many approaches have been utilized to accelerate natural polymer aging and gain necessary engineering data in a reasonable time frame.

The essence of any accelerated aging methodology begins with an understanding of the stresses applied to the polymer during service and how those stresses may affect aging properties. Some typical polymeric stressors include thermal, oxidative, chemical, and physical stresses. Polymer degradation can be modeled as a series of kinetically controlled chemical reactions. Generally, successful accelerated aging methodology intensifies the primary stressors in a controlled manner in order to increase the rate of the overall rate-controlling reaction(s). As analytical methodologies have become ever more sensitive it has become possible to detect the chemical changes which are precursors to polymer degradation, allowing rapid determination of degradation kinetics on very small samples. Once the degradation kinetics are measured, the kinetic data can be used to create kinetic models which allow predictions of degradation rates at normal use temperatures.

The main stressors for aging and degradation of implanted meshes include oxidation and mechanical load. Since the job of the mesh is to support weakened human tissue, it is under constant stress. By performing accelerated testing to measure the rate of oxidation while the sample is not under mechanical stress, we realize that the data is heavily biased to yield data that would predict unrealistically long life. However, it is my expert opinion that the data is still useful, at least for sample to sample comparison, to gain information regarding mesh oxidation resistance variability.

The accelerated method selected to compare the oxidation resistance of the Ethicon meshes is ASTM D3895 "Oxidative Induction Time using Differentia Scanning Calorimetry (DSC)" or OIT. This is a standard test method that is widely followed and accepted in my field. I utilize this

[30] Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients"; Journal Biomed Mater Res Part B: Applied Biomaterials 91B: 1 - 12, (2015).

testing procedure extensively in my profession. The method is used to determine whether polyolefin resins such as polyethylene and PP are appropriately stabilized. The method involves placing a small (~10 milligrams) fiber of the mesh inside a very sensitive instrument called a differential scanning calorimeter (DSC). The instrument detects when chemical oxidation occurs because chemical oxidation gives off heat. The mesh sample is heated to 200°C under pure nitrogen and then the atmosphere inside the instrument is changed to oxygen. The OIT for the sample is the time it takes before an exotherm to be detected. As long as the antioxidants are present in the sample protecting the PP against oxidation, no exotherm is detected. However, the detection of an exotherm means that the antioxidants have been depleted and the PP is undergoing rapid oxidative degradation. A graph showing the output data from an OIT test of one of the Ethicon mesh samples is shown in Figure 2. In the Ethicon mesh sample shown in Figure 2, notice that a slight exotherm is detected several minutes before the main catastrophic OIT exotherm. The first point of exotherm detection is the incipient surface oxidation temperature (ISOT), which derives from the OIT test. The OIT test follows ASTM D3895. The ASTM D3895 test has been relied on for many years for polyethylene and polypropylene plastics. The test is used by companies when designing a product to make sure there is an appropriate level of stabilizer in a product so it will not fail in the end use.

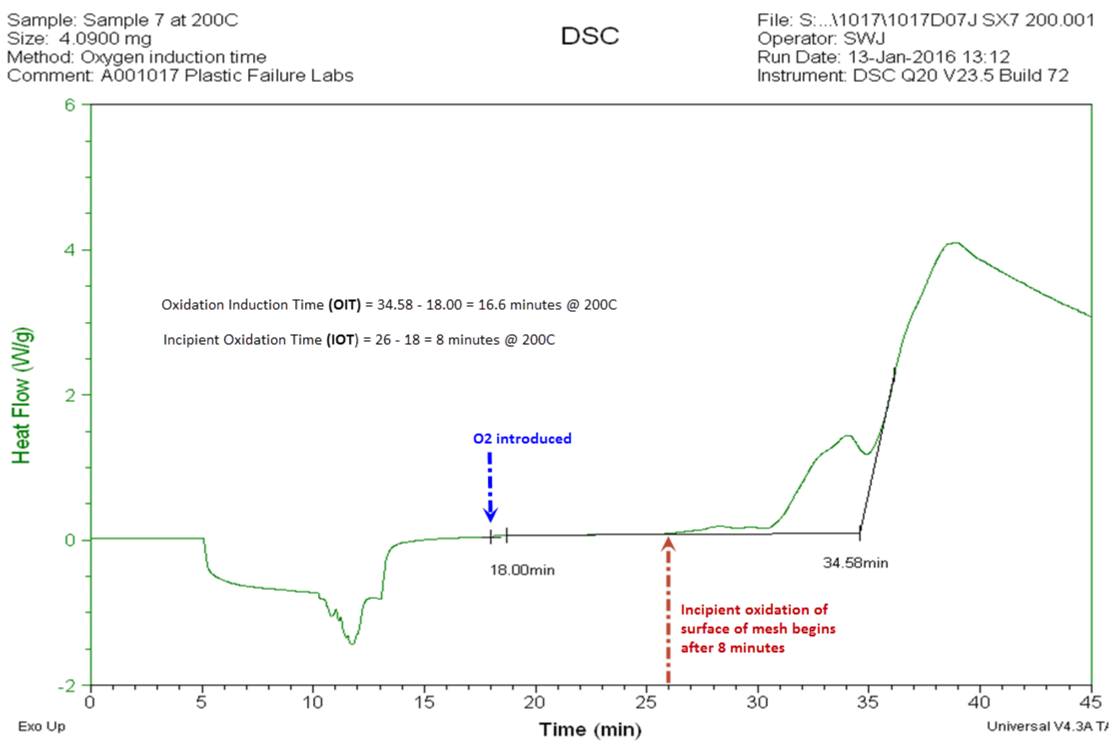


Figure 2. OIT test result on Ethicon mesh Gynecare TVT 810041BL, Lot 3405405. After 8 minutes of exposure to oxygen, incipient oxidation/degradation begins. After 16.6 minutes catastrophic oxidation takes place.

Ten different samples of Ethicon meshes were received from Counsel using an appropriate Chain of Custody. The OIT and ISOT of each mesh sample were measured. Significant variability was

found between the oxidative resistances of the ten meshes. As mentioned previously, the oxidative process begins rapidly on the mesh surface causing embrittlement due to degradation.

It should be pointed out that the OIT testing was performed in an environment where there is no mechanical stress[31] and no loss of antioxidant occurred due to migration from the surface into a liquid environment (like inside the body). Therefore the OIT data is a best case situation because the only mechanism for loss of antioxidant during the OIT tests is chemical reaction; i.e., loss by migration into body fluids is not taken into account. We know from the literature that migration of the antioxidant from the plastic into the surrounding medium is significant.[32] A study of polyolefin resins stabilized with Santonox R (antioxidant present in the PP at issue) found that, in oxygenated water, the Santanox R migrates from the surface of the plastic into the water. The study states: "The loss of Santonox R in samples exposed to water saturated with air was faster than for the samples exposed to oxygen-free water. This was due to increased mass transport of the antioxidant from the polymer phase boundary to the water phase when oxygen was present.... Results obtained by liquid chromatography of extracts confirmed that the gradual decrease in OIT with increasing ageing time was due to migration of antioxidant to the surrounding medium."[33]

XI. CORRELATION OF THE LEVEL OF ANTIOXIDANTS IN MESH SAMPLES WITH OIT

The antioxidants present in the 10 meshes were then extracted from the mesh using methylene chloride solvent. The ten samples were all extracted at the same time for 72 hours by sonication of approximately the same weight of mesh sample in approximately the same weight of methylene chloride solvent (containing an internal standard). The ten extracts were then analyzed using GC-MS to identify and quantify the relative amount of Santanox R antioxidant present in the mesh samples. The variation in the amount of Santanox R present in the ten mesh samples was significant and correlated with the variation in the OIT of the same mesh samples.

XII. ETHICON DOCUMENTS SUPPORT MESH DEGRADATION

I have reviewed internal Ethicon documents regarding outcomes associated with the implantation of Prolene sutures in canine explant studies.[34] These internal Ethicon studies revealed cracking and deformation of the Prolene sutures in response to oxidation and embrittlement. I have also reviewed internal Ethicon documents regarding Ethicon human

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[31] "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM.
[32] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[33] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[34] Eth.Mesh.12729337 ("Five Year Results from Ten Year Prolene Study"); Eth.Mesh.07690752 ("Seven Year Data for Ten Year Prolene Study"); Eth.Mesh.05453719; Eth.Mesh.09557798; Eth.Mesh.113361184 (Protocol of 10 Year In Vivo Dog Study); Eth.Mesh.11336071 ("2 Year Dog Study Interim Report"); Eth.Mesh.11336165 (5 Year Data): Eth.Mesh.09888187 (7 Year Data); Eth.Mesh.11336181 ("Interim Report on the Physical Testing").

explant studies involving Prolene sutures from the 1980s which show Prolene's vulnerability to oxidative changes.[35] The results of these studies are consistent with my opinions in this case.

XIII. EXPERT OPINION

It is my expert opinion within a reasonable degree of scientific certainty that Ethicon knew or should have known that PP was not an appropriate material for use in permanent medical implants of transvaginal mesh. My opinion is independently supported in the scientific literature, by my peers and in my field of expertise. The testing I performed using written ASTM standards and followed well-established methodologies that have existed in my field for decades. The testing and analyses that I have performed as part of my work in this case provides further support for my opinions and was accessible and available to Ethicon when they were designing their PP mesh devices for SUI and POP treatment. Ethicon could have performed this testing when designing these devices. Had Ethicon performed this testing as a reasonable medical device manufacturer, it would have detected a so-called "red flag" alerting it to both the degradation of the PP mesh, the reduced life expectancy of the product, and the leaching / use of the antioxidant package in the PP resin. Ethicon then should have, as a reasonable manufacturer, performed additional tests to determine whether the PP would withstand permanent implantation in the body. Ethicon's failure to do so deviates from the standards of a reasonable company and in this case jeopardized the health of the women receiving their products. This opinion is based upon my decades of experience working with plastics, my testing of Ethicon meshes, my review and knowledge of the science and literature in my field of expertise and my review of the documents listed in Section XVI.

XIV. COMPENSATION

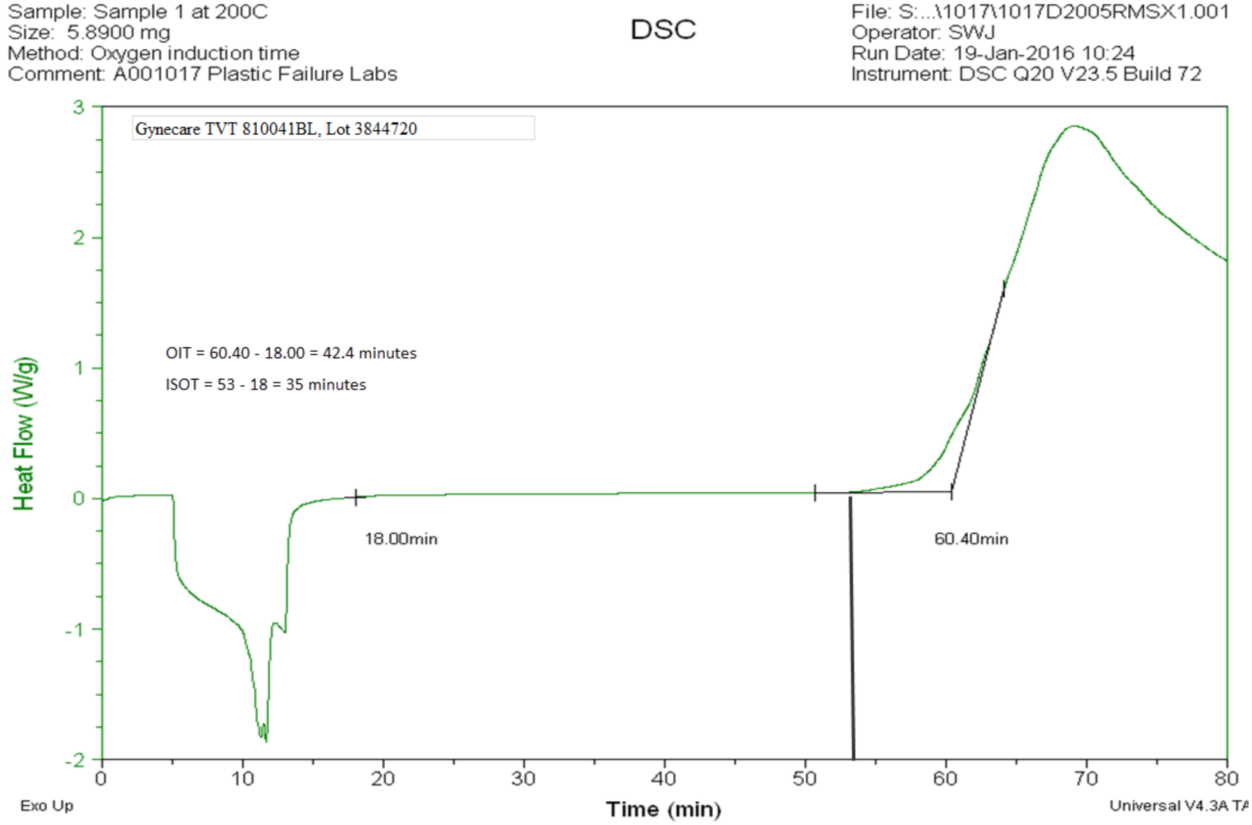
I received a $3500 retainer check on October 19th 2015 as a deposit toward my expert services in this matter. I am being paid $375/hour for my expert services performed from my office. I will be paid $550 for oral testimony under oath in this matter.

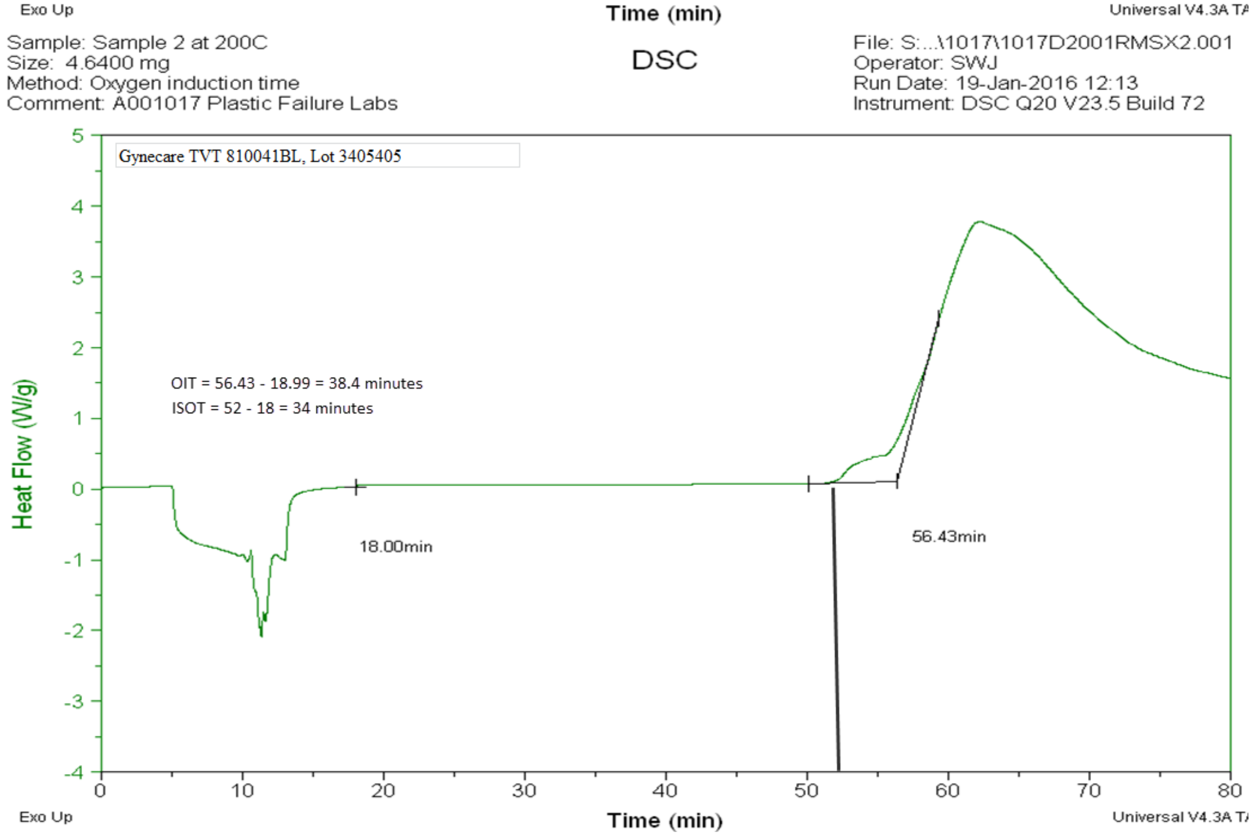
XV. FACTS AND DATA CONSIDERED

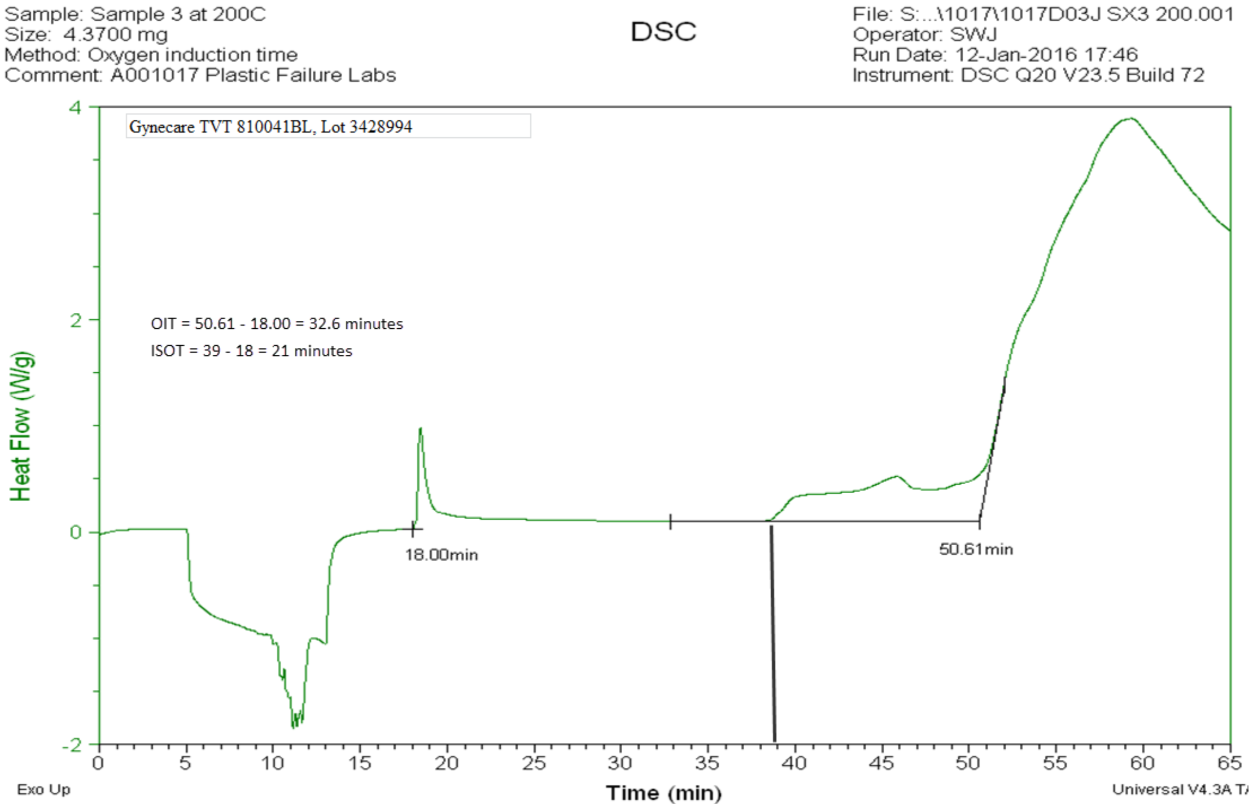
In addition to the materials cited in this report, I have also considered the materials listed in Exhibit B in forming my opinions in this case.

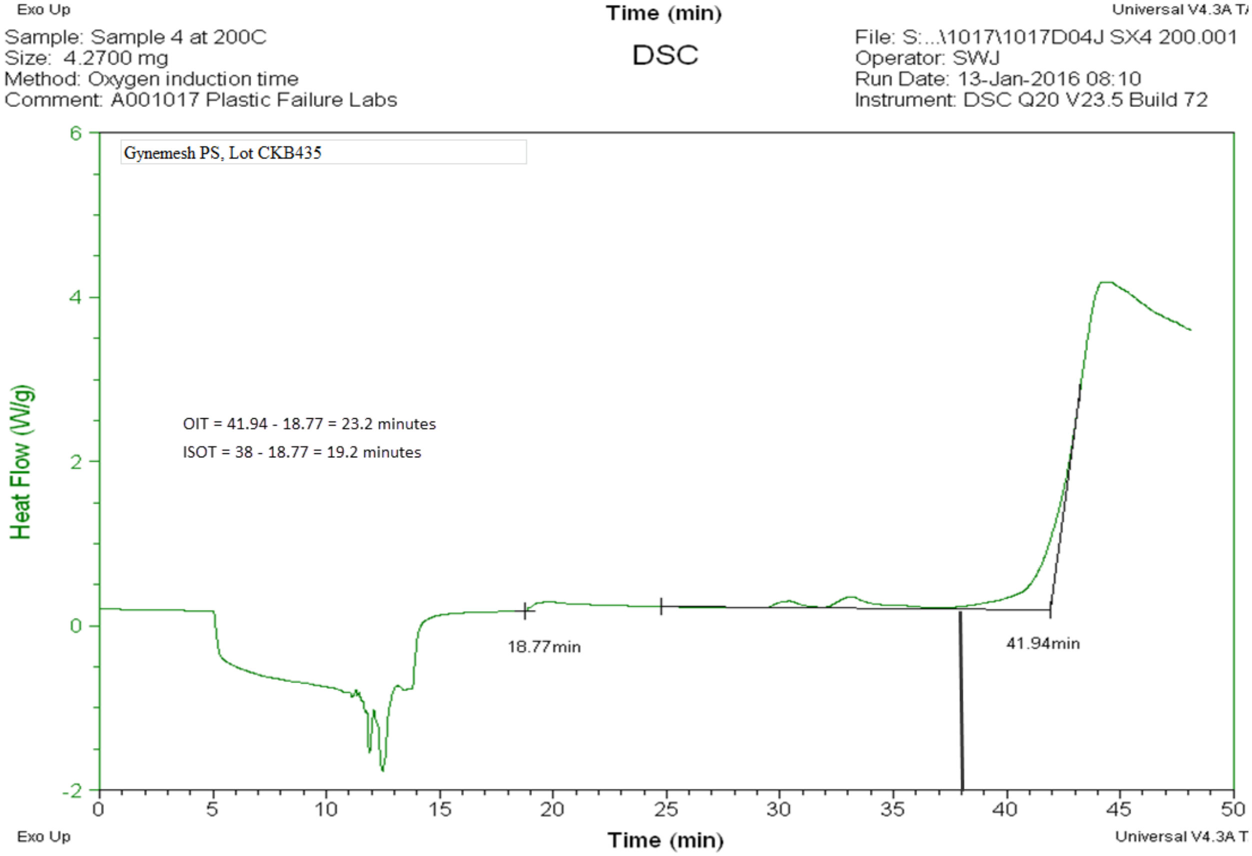
XVI. APPENDIX

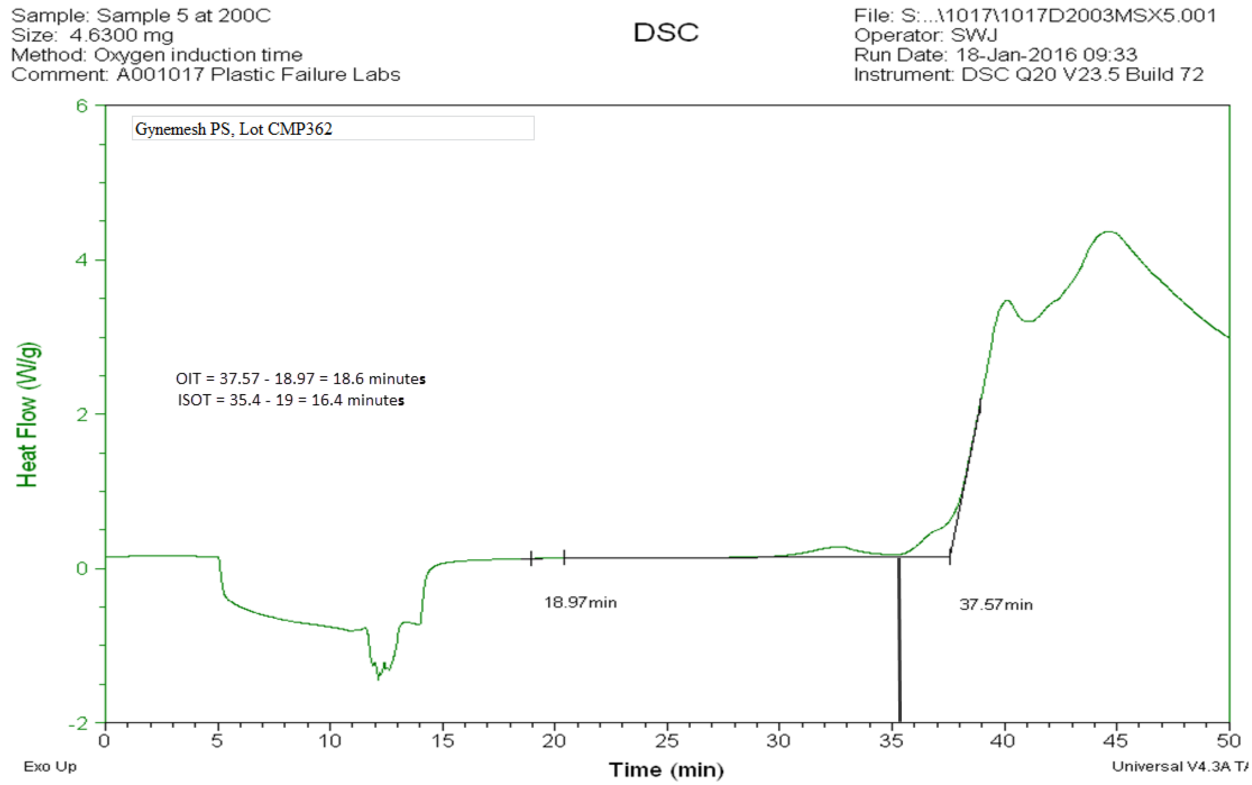
[35] Eth.Mesh.12831391 ("IR Microscopy of Explanted Prolene Received from Prof. R. Guidoin").

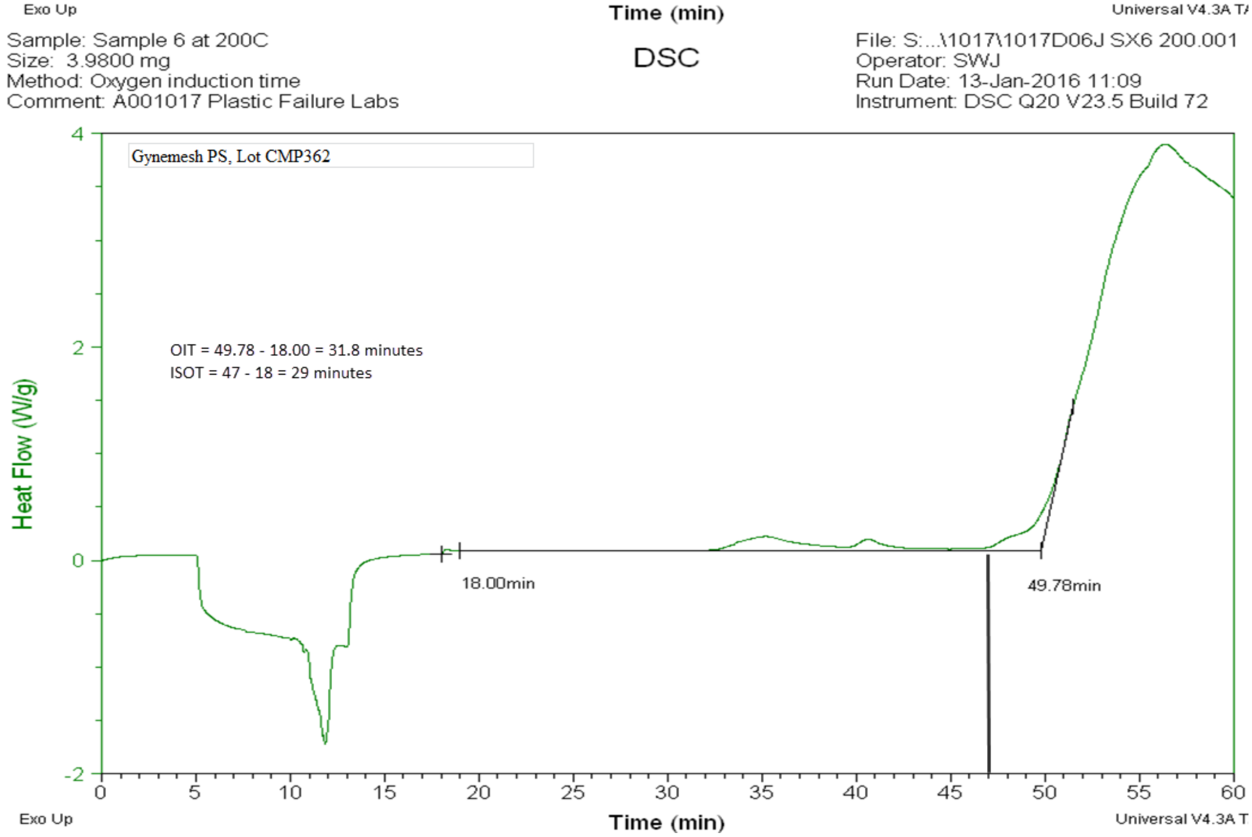

Sample: Sample 1 at 200C
Size: 5.8900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D2005RMSX1.001
Operator: SWJ
Run Date: 19-Jan-2016 10:24
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT 810041BL, Lot 3844720
OIT = 60.40 - 18.00 = 42.4 minutes
ISOT = 53 - 18 = 35 minutes
18.00min
60.40min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA

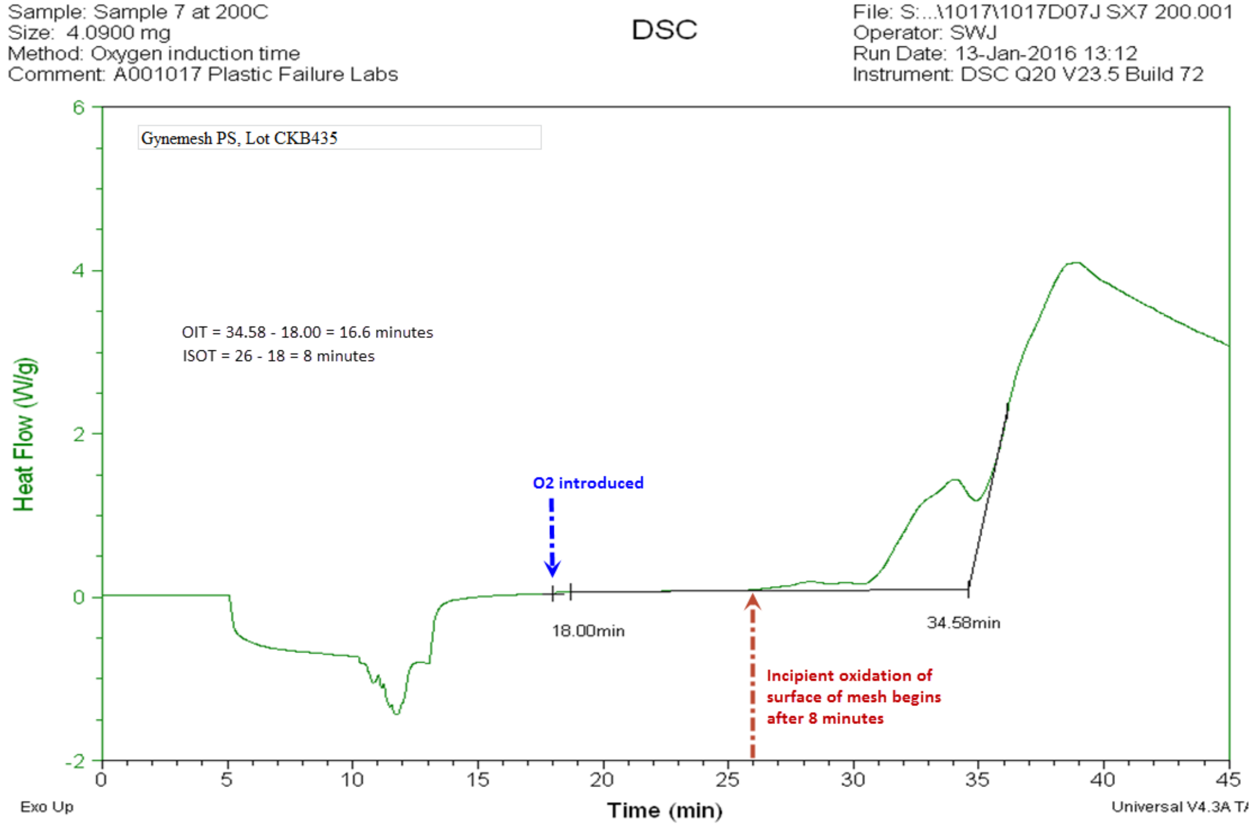

Sample: Sample 2 at 200C
Size: 4.6400 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D2001RMSX2.001
Operator: SWJ
Run Date: 19-Jan-2016 12:13
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT 810041BL, Lot 3405405
OIT = 56.43 - 18.99 = 38.4 minutes
ISOT = 52 - 18 = 34 minutes
18.00min
56.43min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA

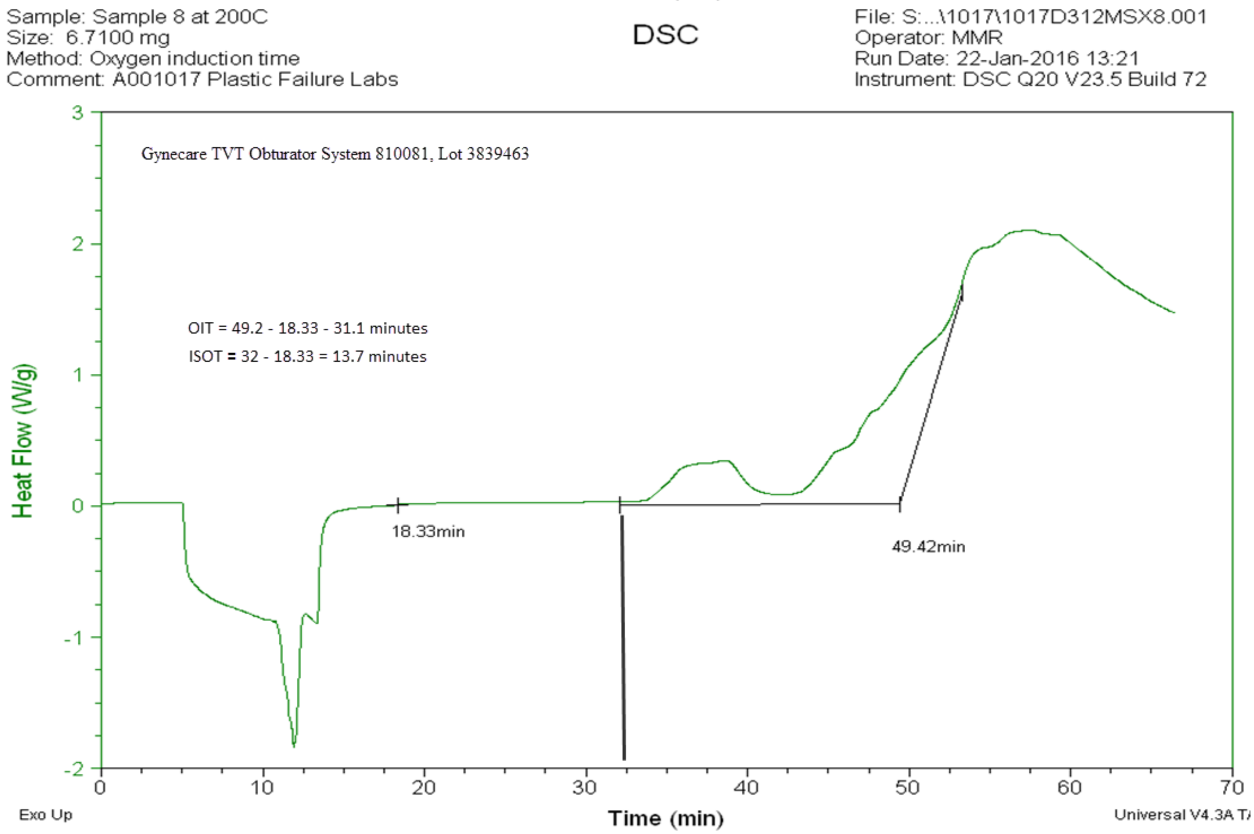

Sample: Sample 3 at 200C
Size: 4.3700 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D03J SX3 200.001
Operator: SWJ
Run Date: 12-Jan-2016 17:46
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT 810041BL, Lot 3428994
OIT = 50.61 - 18.00 = 32.6 minutes
ISOT = 39 - 18 = 21 minutes
18.00min
50.61min
Heat Flow (W/g)
Exo Up
Time (min)
Universal V4.3A TA

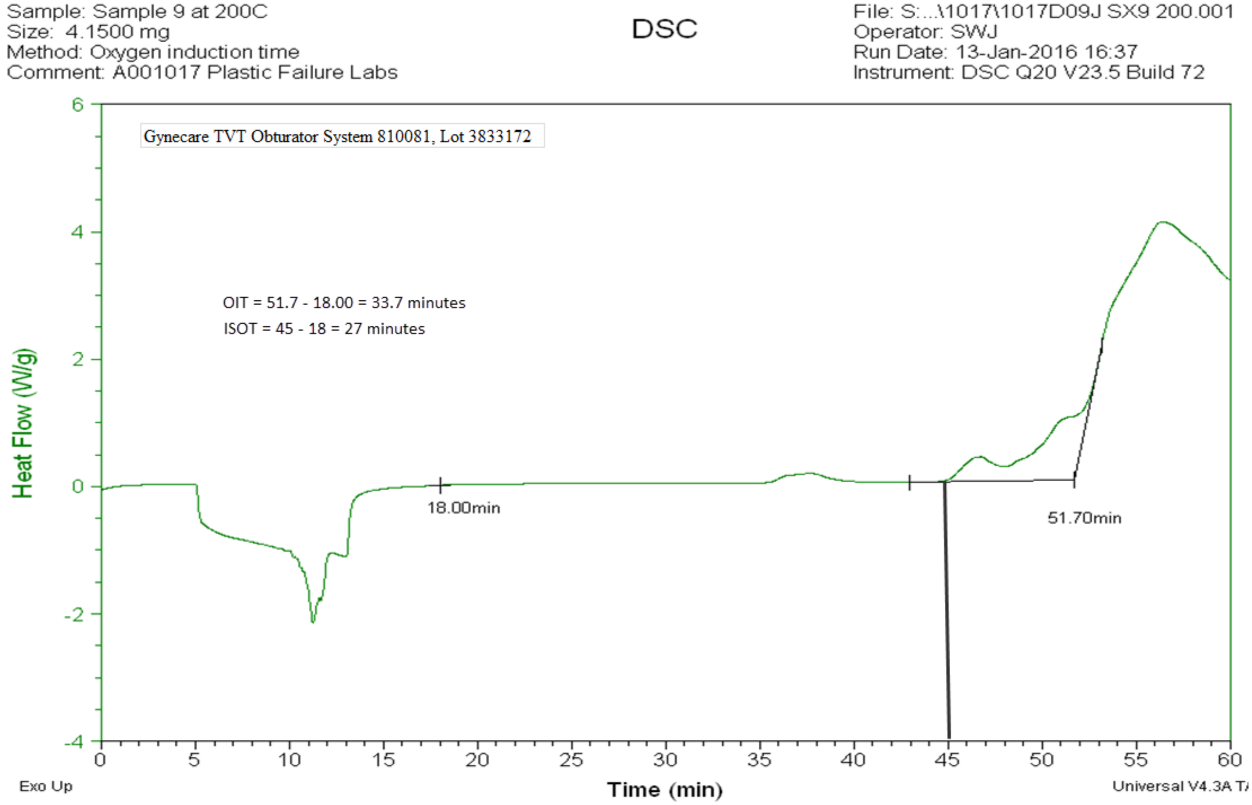

Sample: Sample 4 at 200C
Size: 4.2700 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D04J SX4 200.001
Operator: SWJ
Run Date: 13-Jan-2016 08:10
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CKB435
OIT = 41.94 - 18.77 = 23.2 minutes
ISOT = 38 - 18.77 = 19.2 minutes
18.77min
41.94min
Heat Flow (W/g)
Exo Up
Time (min)
Universal V4.3A T

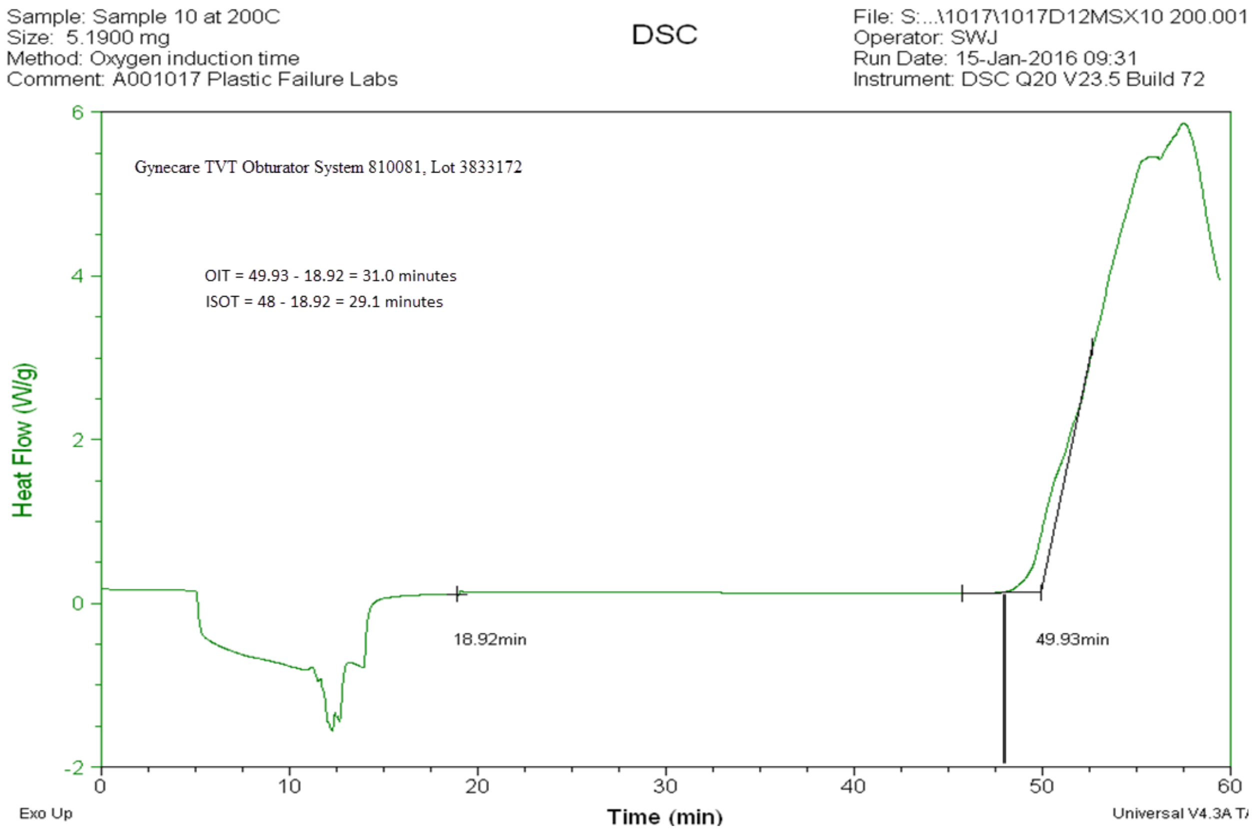

Sample: Sample 5 at 200C
Size: 4.6300 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D2003MSX5.001
Operator: SWJ
Run Date: 18-Jan-2016 09:33
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CMP362
OIT = 37.57 - 18.97 = 18.6 minutes
ISOT = 35.4 - 19 = 16.4 minutes
18.97min
37.57min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA


Sample: Sample 6 at 200C
Size: 3.9800 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D06J SX6 200.001
Operator: SWJ
Run Date: 13-Jan-2016 11:09
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CMP362
OIT = 49.78 - 18.00 = 31.8 minutes
ISOT = 47 - 18 = 29 minutes
18.00min
49.78min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T


Sample: Sample 7 at 200C
Size: 4.0900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D07J SX7 200.001
Operator: SWJ
Run Date: 13-Jan-2016 13:12
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CKB435
OIT = 34.58 - 18.00 = 16.6 minutes
ISOT = 26 - 18 = 8 minutes
O2 introduced
18.00min
34.58min
Incipient oxidation of surface of mesh begins after 8 minutes
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA


Sample: Sample 8 at 200C
Size: 6.7100 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D312MSX8.001
Operator: MMR
Run Date: 22-Jan-2016 13:21
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT Obturator System 810081, Lot 3839463
OIT = 49.2 - 18.33 - 31.1 minutes
ISOT = 32 - 18.33 = 13.7 minutes
18.33min
49.42min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA


Sample: Sample 9 at 200C
Size: 4.1500 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D09J SX9 200.001
Operator: SWJ
Run Date: 13-Jan-2016 16:37
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT Obturator System 810081, Lot 3833172
OIT = 51.7 - 18.00 = 33.7 minutes
ISOT = 45 - 18 = 27 minutes
18.00min
51.70min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T/


Sample: Sample 10 at 200C
Size: 5.1900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D12MSX10 200.001
Operator: SWJ
Run Date: 15-Jan-2016 09:31
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT Obturator System 810081, Lot 3833172
OIT = 49.93 - 18.92 = 31.0 minutes
ISOT = 48 - 18.92 = 29.1 minutes
18.92min
49.93min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T/

XVII. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN THE LAST FOUR YEARS

Fabara v GoFit

Boiko v Kikkerland

Jones v Heil

Patients v AMS

Esplanade v Fifth & Continental

Rubitsky v BMW

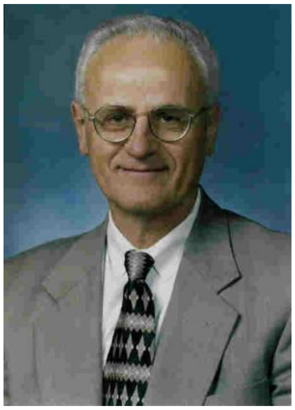
Yucatan Foods v Berry Plastics

Sincerely,

Duane Priddy, Ph.D.

EXHIBIT A

Curriculum Vitae



DUANE B. PRIDDY, Ph.D.

Founder & CEO
Plastic Expert Group &
Plastic Failure Labs, Inc.
Tel: +1. 989.385.2355
Email: priddy@plasticexpert.com
Web: www.plasticexpert.com

SYNOPSIS

Dr. Duane B. Priddy is the founder and CEO of Plastic Expert Group. He has spent over 40 years in the Plastics Industry as a leading authority on plastic and composite part failure. He worked for Dow Plastics as one of their leading Principal Scientist. Dr. Priddy is a world renowned scientist and author as evidenced by his many awards including Dow's Lifetime Achievement Award. In 2001 he was awarded "Fellow" by the Polymeric Materials Division of the American Chemical Society. In 2008 he was awarded "Fellow" by the Society of Plastics Engineers for his pioneering work in the development of Plastic Science & Technology. He is a member of ASM International (a society of Material Scientists), the American Chemical Society Polymer Chemistry and Polymeric Materials Divisions, the International Association of Plumbing and Mechanical Officials, the National Association of Subrogation Professionals, the Society of Fire Protection Engineers, the Failure Analysis Division of the Society of Plastics Engineers, the Institute of Packaging Professionals, and the Society of Automotive Engineers. Dr. Priddy has provided expert services in over 150 litigations involving plastics and composites since 2003. He is one of the top plastic failure experts in the world having analyzed hundreds of plastic and composite parts including, pipes, food packages, bottles, tanks, latches, toys, medical devices, exercise equipment, automotive parts, pulleys, chairs, and stools. Dr. Priddy has served as an expert in over 150 litigations and has authored >100 scientific papers, >60 US Patents, a book entitled "Modern Styrenic Plastics", and several encyclopedia articles on chemicals and plastics.

CONSULTANT AND EXPERT WITNESS ON CHEMICALS AND PLASTICS

- Forensic analysis/testing of plastic and composite parts
- Manufacturing processes for plastic bottles including extrusion blow-molding, injection blow-molding, and stretch blow-molding
- Root cause analysis of CPVC fire suppression system failures
- Exercise equipment failure
- Plastic piping products including ABS, PVC, CPVC, PEX, PP, PVDC, and HDPE
- Additives for plastics including antioxidants and UV stabilizers
- Design of plastic parts to meet the requirements of the application
- Fracture mechanics of plastic materials and composites
- Chemical resistance/degradation of plastics and elastomers
- Discoloration and loss of clarity of plastics

- Plastic part and package design and stress analysis
- Polymer blends and compounding
- Polyolefin based resins and applications
- Additives for improved adhesion in polymer blends and composites
- Chemicals and Plastics R&D
- Monomer stabilization and polymerization
- Molding and extrusion of plastics including foams and films
- UV, thermal, and environmental degradation of chemicals and plastics
- Plastic flammability and plastic flame retardant formulations
- Migration of chemicals and additives from plastics
- Chemicals and plastics for medical use
- Composite and nanocomposite materials including carbon fiber composites
- Permeability (vapors and odors) of plastics
- Plastics used in medical applications
- Failure of fiber reinforced plastics (FRP) and composites
- Material Selection (choosing the right plastic for the application)

EDUCATION

- Ph.D. Organic Chemistry - 1971 - Michigan State University
- BA Chemistry - 1966 - Olivet College, Olivet, MI

MAIN ACCOMPLISHMENTS

- > 60 Issued United States Patents
- >100 Publications including 5 encyclopedia articles and 8 book chapters
- Author/Editor of book “Modern Styrenic Polymers” Wiley 2003

WORK EXPERIENCE

- Over 30 years experience as a leading Research Scientist in Dow Chemical serving as Principal Scientist for Dow’s Polycarbonate and Styrenic Plastics Businesses.
- Principal Scientist for Dow Plastics Additives and Blends Group
- CEO of Plastic Failure Labs - 2003 to present
- PVC/CPVC Pipe Failure Consultant for Charlotte Pipe & Foundry – 2008 to 2014
- Consultant for SpecialChem/Omnexus – 2004 to present

ACADEMIC

- Adjunct Professor at Michigan Technological University – 1988 - 1995
- Adjunct Professor at Central Michigan University – 1988 to present

HONORS & AWARDS

- Awarded “Fellow” of the Society of Plastics Engineers (SPE) 2008
- Awarded “Lifetime Achievement Award” by Dow Chemical – 2001
- Awarded “Fellow” National American Chemical Society (ACS) PMSE – 2001

Dr. Duane Priddy's Litigation Experience in the Past Five Years

Matter	Subject	Pltf	Dfns	Service	Year
Women v Ethicon mesh	Tranvaginal mesh failure	x		C/EO	2016
Fabara v GoFit	Exercise ball failure	x		EO/D	2016
Randy White v Swisher Hygiene	Bottle closure failure	x		C	2016
American Family Ins v Rick Plumbing	PEX tubing failure		x	C	2015
Adams v Walmart & Cargill Meats	Food packaging failure		x	C	2015
Lopez v Save Mart	Grocery Bag failure		x	C	2015
Frazier v Dunkin Donuts	Coffee cup failure		x	C	2015
Trump Hollywood v Allied et al	CPVC failure	x		EO	2015
Equistar v Westlake	Patent infringement		x	C	2015
Tripp Harrison Gallery v Allied et al	CPVC failure	x		C	2015
199 RiverOaks v Vistacom	CPVC failure		x	EO	2015
CNRL v ShawCor	Insulated Pipe Failure		x	C	2015
Atlantic Sprinkler v IPEX	CPVC failure		x	EO	2015
Boiko v Kikkerland	Step stool failure	x		EO/D	2015
Jones v Heil	FRP part failure		x	EO/D	2015
Levitan v Ball Dynamics	Exercise ball failure	x		EO	2015
CNH v Arlon	PVC sign failure	x		C	2015
Jones v Aultman Hospital	Catheter failure		x	C	2015
Poshard v Great Shapes	Exercise ball failure		x	EO	2015
Lopez v SaveMart	Grocery bag failure		x	C	2015
Washington Square HOA. v. Big-D	Plastic pipe and gasket degradation		x	EO	2015
Patients v AMS	PP medical device failure	x		C/D	2014
PrePlastics v. Ashland	Plastic quality dispute	x		C	2014
Lexington Ins v Browning Constr	CPVC pipe failure	x		EO	2014
MMPA v Marshall Film	Bag failure		x	C	2014
Selby v Makray Manufacturing	Microwave Bowl Failure	x		EO	2014
Forsyth II v Simplex Grinnel	CPVC pipe failure	x		EO	2014
Durbin v Kennedy International	Stool failure	x		EO	2014
Webber v Kennedy International	Stool failure	x		EO	2014
Grand Dunes v Prestige	CPVC pipe failure	x		EO	2014
Maitin v Publix	Grocery bag failure	x		C	2014
Borman v Embark Fitness	Exercise ball failure	x		EO	2014
Dowhaluk v Everlast	Exercise ball failure	x		EO	2014
Cop v Bell Sports	Exercise ball failure	x		EO	2014
Pulte Homes v NIBCO	PEX pipe failure	x		C	2014
Settlers Loop v Eco Existance	CPVC pipe failure		x	C	2014
SubZero v. KX	Water filter failure	x		C	2014
Dowhaluk v EB Brands	Exercise ball failure	x		C	2014
Buckley v Peg Perego	Toy breakage / personal injury		x	C	2014
Nealson v McDonalds/Pactiv	Injury caused by defective spoon	x		EO	2014
Esplanade v Fifth & Continental	CPVC fire sprinkler system defects	x		EO/CT	2013
LeFluer v Burger King & Dart	EPS foam Coffee Cup Failure	x		EO	2013
Post Properties v FLSA	CPVC fire sprinkler failure	x		C	2013
Grove Construction v Furguson	PVC pipe failure	x		EO	2013
Pure Ins. V Olin	Hose failure		x	C	2013
Rubitsky v BMW	Automotive composite part failure	x		C/D	2013
Pedvin v Ossur	Knee brace failure	x		C	2013
Schug v Bamboo Leaf	Chair failure	x		C	2013
Yucatan Food v Berry Plastics	Food Packaging Failure	x		C/CT	2013

C = consultant; EO = expert opinion; D = deposition; CT = courtroom testimony

Scientific Articles and Publications

Duane Priddy, Rowland Hall, Dan Beaudoin**, Selecting the Best Remediation Option for Failing CPVC Piping Systems,** Society of Plastic Engineers ANTEC 2016, passed peer review.

Duane Priddy and Tom Peeler, **Root Cause of Failure of an EPS Foam Coffee Cup,** Society of Plastic Engineers ANTEC 2014, Paper# 1838094.

Duane Priddy, **Why Do Some PVC Foam Exercise Balls Explode While Others Do Not?,** Society of Plastic Engineers ANTEC 2013, Paper# 1536954.

Duane Priddy, **Forensic Analysis of CPVC Fire Sprinkler Piping,** Subrogator, Spring/Summer 2012, pp. 72 – 77.

Duane Priddy, **When CPVC Pipes and Fittings Fail in Hydronic Heating Systems**, Plastics Engineering, April 2012, pp. 4 – 9.

Duane Priddy, **Root Cause of Occasional Failure of CPVC Pipes Used in Hydronic Heating Systems**, Society of Plastics Engineers Annual Technical Conference Proceedings 2011, pp. 1404-9.

Duane Priddy, **Why Do PVC/CPVC Pipes Occasionally Fail?**, available on the internet at: http://www.plasticfailure.com/user/Why_Plastic_Pipes_Fail.pdf

Saczalski, Ken, West, Mark, and Duane Priddy, **Damage Analysis Technique for Evaluation of Plastic Seats in Handicapped Mobility Devices**, Proceedings of the SAMPE Tech 2011 Conference, Session on Design, Analysis, and Simulation II, Fort Worth, Texas October 17-20. Obtain a copy of this paper at http://plasticfailure.com/portfolio/failure-analysis-plastic-seat/ **.**

Duane Priddy, **Styrene plastics.** Kirk-Othmer Encyclopedia of Chemical Technology (5th Edition) (2007), 23, 358-416.

Duane Priddy, **Why Do Plastics Occasionally Fail?**, available on the internet at: http://www.plasticfailure.com/user/WhyPlasticsFail.pdf

Howell, B. A.; Powers, J. J.; Duane Priddy, **Thermal decomposition of cycloadducts of vinylnaphthalenes with electron-deficient dienophiles.** Center for Applications in Polymer Science, Central Michigan University, Mt. Pleasant, MI, USA. Journal of Thermal Analysis and Calorimetry (2006), 85(1), 141-143

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Most Recent 50 US Patents

PAT. NO.	Title
7,320,201	Hollow plastic block assembly for wall construction
6,573,349	High molecular weight monovinylidene aromatic polymers with good processability
6,503,992	Phosphorous-containing monomers and flame retardant high impact monovinylidene aromatic polymer compositions derived therefrom
6,214,945	Process for producing high molecular weight styrenic polymers and polymodal compositions
6,156,855	Production of branched polymers
6,084,044	Catalyzed process for producing high molecular weight monovinylidene

aromatic polymers

5,990,255 High molecular weight polysytrene production by vinyl acid catalyzed free radical polymerization

5,962,605 High molecular weight polystyrene production by vinyl acid catalyzed free radical polymerization

5,959,033 Polymers containing highly grafted rubbers

5,948,874 Acid catalyzed polymerization

5,721,320 In situ block copolymer formation during polymerization of a vinyl aromatic monomer

5,677,388 Difunctional living free radical polymerization initiators

5,663,252 Process for preparing a branched polymer from a vinyl aromatic monomer

5,650,106 Extruded foams having a monovinyl aromatic polymer with a broad molecular weight distribution

5,627,248 Difunctional living free radical polymerization initiators

5,618,900 Free radical polymerization

5,473,031 Branched polystyrene production by free radical bulk polymerization

5,408,023 Preparation of modified vinyl polymers

5,347,055 Oligomers of styrene as flegmatizers for organic peroxides

5,194,658 Process for making 2-amino-3-methyl-1-naphthalenecarbonitrile

5,194,527 Preparation of ketone containing photodegradable polymers

5,187,249 Degradable B-alkoxy vinyl ketone resin composition

5,145,924 Free radical polymerization of styrene monomer

5,115,058 Bio- and photo-degradable resin composition

5,115,055 Hydroperoxide catalyzed free radical polymerization of vinyl aromatic monomers

5,087,738 Multifunctional cyclobutarene peroxide polymerization initiators

5,079,322 Multifunctional cyclobutarene peroxide polymerization initiators

5,034,485 Multifunctional cyclobutarene peroxide polymerization initiators

4,910,274 Preparation of monohydroxy-containing polymers

4,895,907 Polymerization process using bisquinone peroxide catalyst

4,859,748 Process for anionic polymerization in a continuous stirred tank reactor

4,812,530 Polyether-polycarbonate-polyether triblock copolymers

4,812,514 Polymer blends

4,806,599 Polyolefin/polycarbonate/polyolefin triblock copolymers

4,789,730 Preparation of polycarbonate having reduced cyclic carbonate oligomer content

4,725,654 Process for anionic polymerization

4,704,431 Blends of polypropylene and vinylaromatic/.alpha.-methylstyrene copolymers

4,647,632 Production of copolymers of .alpha.-methylstyrene

4,572,819 Apparatus for anionic polymerization wherein the molecular weight of the polymer is closely controlled

4,389,517 Hydrogenation of phenylacetylene prior to styrene polymerization

4,288,379 Hydrocarbon polyl gem-bis(t-alkylperoxy)alkanoates derived from .beta.-keto-acids

4,275,182 Process for the preparation of improved styrene acrylic acid copolymers

4,195,169 Devolatilizing polymers of styrene and acrylic or methacrylic acid

4,178,263 Organic peroxide compositions

4,131,728 Method for polymerizing olefinically unsaturated monomers employing a catalyst composition comprising (a) shock-sensitive organic peroxide and (b) an olefinic unsaturated non-homopolymerizable monomer

4,087,599 Preparation of a water-soluble polyvinylbenzyl quaternary ammonium halide

4,052,464 Process for the manufacture of di-t-butylperoxy ketals

4,029,685 Peroxy esters of pyromellitic acid

EXHIBIT B

FACTS AND DATA CONSIDERED

DATE	DOCUMENT	BATES BEG	BATES END
	TVT Abbrevo IFU	ETH.MESH.02341203	
9/22/1987	Lab Notebook pages from 1987 Study of Human	DEPO.Eth.Mesh.00000	
	Guidoin Explant Report	Depo.eth.mesh.00004 755	
	ASTM D3895	N/A	
	ASTM Standard Test Method for Stiffness of Fabrics	Designation: D 1388 – 96 (Reapproved 2002)	
0/0/2010	Richter NEJM article	Eth. Mesh.02594075	
		ETH.MESH . 00219861	
		ETH.MESH . 00748451	
		ETH.MESH . 00836161	
		ETH.MESH . 00870466	
		ETH.MESH . 01154126	
		ETH.MESH . 01962174	
		ETH.MESH . 02134849	
		ETH.MESH . 02157879	
		ETH.MESH . 02227368	
		ETH.MESH . 02282833	
		ETH.MESH . 03987419	
		ETH.MESH . 04013853	
		ETH.MESH . 04038032	
		ETH.MESH . 05644163	
	Risk Assessment	ETH.MESH . 06195201	ETH.MESH.06195205
		ETH.MESH . 06372356	
		ETH.MESH . 07726704	

		ETH.MESH . 07928207	
		ETH.MESH . 07930355	
	Braskem MSDS	ETH.MESH . 10630803	ETH.MESH.10630808
		ETH.MESH . 11298411	
		ETH.MESH . 11298469	
		ETH.MESH . 11298478	
		ETH.MESH . 11298489	
		ETH.MESH . 11298513	
		ETH.MESH . 13345921	
		ETH.MESH . 14234636	
		ETH.MESH . 14234651	
		ETH.MESH . 14237478	
	Mesh Safety Report	ETH.MESH . 14442958	ETH.MESH.14442976
		ETH.MESH . 21989844	
		ETH.MESH . 21989844	
0/0/2012	Barber article	Eth.Mesh .10282645	
8/23/2007	Zaddem V email re macroporous - lower limit of pore size	ETH.MESH.00000272	ETH.MESH.00000272
8/9/2005	Selman 2005 Performance and Development Plan Summary	ETH.MESH.00000298	ETH.MESH.00000364
9/22/1987	Lab Notebook pages Re Prolene Explants	ETH.MESH.00000367	ETH.MESH.00000368
11/22/2007	Performance Qualificagtion Protocol: Gynecare Prolift +M Sous-Ensemble	ETH.MESH.00000428	ETH.MESH.00000428
3/5/2009	Interim report mesh explants pelvic floor repair	Eth.Mesh.00006636	
04/??/08	Klosterhalfen Interim report mesh explants pelvic floor repair	ETH.MESH.00006636	ETH.MESH.00006636
	Presentation: Stand & Deliver Pelvic Floor Repair	ETH.MESH.00006796	ETH.MESH.00006809
11/18/2008	Pelvic Floor Repair Online Training Course Second Draft Content Document	ETH.MESH.00008072	ETH.MESH.00008072
	Annotated Prolift +M List of potential claims	ETH.MESH.00008631	ETH.MESH.00008631
	Cosson, et al, Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int. Urogynecol J (2003) 14: 169-178	Eth.Mesh.00015598	Eth.Mesh.00015607

12/8/2003	510(k) Summary	ETH.MESH.00019863	ETH.MESH.00019924
11/28/2005	510(k) premarket notification letter	ETH.MESH.00019925	ETH.MESH.00020019
	Gynecare Prolift Pelvic Floor Repair System presentation	ETH.MESH.00033325	ETH.MESH.00033385
	Dr Lucent session transcript	ETH.MESH.00067356	ETH.MESH.00067363
	Medical Device Risk Management Plan - Revision Hx for PR602-003 Rev 13	ETH.MESH.00070187	ETH.MESH.00070211
1/5/2010	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA	ETH.MESH.00077727	ETH.MESH.00077732
3/7/2007	Flatow J email chain re Lightning 510(k) requirements list	ETH.MESH.00078537	ETH.MESH.00078539
6/29/2010	Clinical Study Report A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prolift +M Pelvic Floor Repair System as a Device for Pelvic Organ Prolapse	ETH.MESH.00080795	ETH.MESH.00080924
??/??/07	Prolift +M IFU	ETH.MESH.00081133	ETH.MESH.00081139
11/9/2010	11/9-11/2010 AAGL Meeting PPT Presentation.	Eth.Mesh.00107688	
11/9/2011	AAGL Las Vegas meeting brochure	ETH.MESH.00107688	ETH.MESH.00107688
	TVT Professional Education Program	ETH.MESH.00156909	ETH.MESH.00156938
??/??/06	No bigger than your palm - brochure	ETH.MESH.00158289	ETH.MESH.00158293
	Memorandum re Copy review submission compliance	ETH.MESH.00159473	ETH.MESH.00159473
5/4/2007	Gynecare TVT Secur System: Key Technical Points	ETH.MESH.00163952	ETH.MESH.00163960
4/18/2006	CER Weisberg - Laser Cut Mesh	ETH.MESH.00167104	ETH.MESH.00167110
2/8/2002	Design Validation Strategy Version 1	ETH.MESH.00199408	ETH.MESH.00199413
11/24/2005	Team conference call notes	ETH.MESH.00208897	ETH.MESH.00208897
11/10/2009	Mini TVT-O Team Meeting	Eth.Mesh.00211038	Eth.Mesh.00211041
11/10/2009	Mini TVT-O Team Meeting Agenda	ETH.MESH.00211038	ETH.MESH.00211041
1/8/2002	Barbolt memo to D'Aversa re Biocompatibility Risk Assessment for Prolene	ETH.MESH.00220333	ETH.MESH.00220336
5/14/2001	TVT-O Design History Book 5 of 7	ETH.MESH.00222779	ETH.MESH.00223267
	TVT-O Design History Book 5 of 7	Eth.Mesh.00222779	
5/14/2001	TVT-O Design History Book 1 of 7	ETH.MESH.00259047	ETH.MESH.00259514
	TVT-O Design History Book 1 of 7	Eth.Mesh.00259047	
12/15/2003	Product Design Safety Assessment Revision 2	ETH.MESH.00259473	ETH.MESH.00259503
5/29/2003	Study description Chart	ETH.MESH.00260020	ETH.MESH.00260021
4/14/2003	Smith,D email chain re Mulberry update	ETH.MESH.00260591	ETH.MESH.00260592
0/0/2003	Email re: lack of clinical data	Eth.Mesh.00260591	
6/9/2003	O'Bryan S email re Mulberry stage gate action item closed	ETH.MESH.00261584	ETH.MESH.00261585
	PPT Presentation titled “The Science of What’s Left Behind: Evidence & Follow-Up of Mesh Use for SUI.”	Eth.Mesh.00271641	
	Nick Franco Naples, FL Presentation: The Science of "What's Left Behind"... Evidence & Follow-Up of Mesh Used for SUI	ETH.MESH.00271641	ETH.MESH.00271641

11/21/2005	Email re: GREAT NEWS FOR TVT LASER CUT MESH!	Eth.Mesh.00301741	Eth.Mesh.00301742
11/21/2005	Lamont D email chain re Great News for TVT Laser Cut Mesh	ETH.MESH.00301741	ETH.MESH.00301742
2/24/2006	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary	ETH.MESH.00302105	ETH.MESH.00302106
2/20/2007	Lamont D email chain re Complaint Summaries	ETH.MESH.00303084	ETH.MESH.00303085
3/5/2008	Lamont D email chain re Gynemesh issue	ETH.MESH.00303944	ETH.MESH.00303945
4/29/2008	Lamont D email chain re Post Launch Reviews	ETH.MESH.00304013	ETH.MESH.00304014
		ETH.MESH.00308747	
3/3/2008	Robinson D email chain re Quality issue with a batch of gynemesh	ETH.MESH.00328895	ETH.MESH.00328901
	- DFMEA	ETH.MESH.00335080	ETH.MESH.00335080
12/18/2008	Lisa B email chain re TVT Patient Brochure Fair Balance EPI Changes	ETH.MESH.00339083	ETH.MESH.00339084
02/??/02	5 Years of Proven Performance	ETH.MESH.00339437	ETH.MESH.00339442
4/1/2009	Email re: TVT-Mini Clinical Support.	Eth.Mesh.00346227	
4/1/2009	Lisa B email re TVT-Mini clinical support	ETH.MESH.00346277	ETH.MESH.00346277
	Excel Spreadsheet of Pain associated with TVT-O.	Eth.Mesh.00354725	
	Spreadsheet re TVT-O pain	ETH.MESH.00354725	ETH.MESH.00354725
??/??/10	pg from Minimally invasive synthetic suburethral sling operation for SUI in women	ETH.MESH.00355087	ETH.MESH.00355087
		ETH.MESH.00360799	
	Revision Hx for PR800-012 Rev 11	ETH.MESH.00363605	ETH.MESH.00363625
1/28/1998	510(k) clearance letter	ETH.MESH.00371496	ETH.MESH.00371594
2/1/2006	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project	ETH.MESH.00394544	ETH.MESH.00394553
5/6/2005	London Brown A email re Laser-cut Mesh	ETH.MESH.00526473	ETH.MESH.00526474
6/23/2006	St. Hilaire P email chain re LCM - Launch Strategy EMEA	ETH.MESH.00526484	ETH.MESH.00526487
5/22/2007	Smith D email chain re TVT Secur EU Experts meeting - feedback & future action	ETH.MESH.00527832	ETH.MESH.00527836
9/27/2010	Shah N email chain re Textile supplier	ETH.MESH.00528621	ETH.MESH.00528626
11/18/2003	Wesiberg Memo to File re Mesh Fraying for TVT Devices	ETH.MESH.00541379	ETH.MESH.00541380
10/18/2010	Caro-Rosado L email chain re Lab results orf Mesh roping evaluation	ETH.MESH.00544657	ETH.MESH.00544658
5/18/2006	Cantimbuhan R email re design transfer checklist dicussion, 05/16/06	ETH.MESH.00554680	ETH.MESH.00554680
2/15/2006	Flatow J email chain re DVer protocol for particle loss	ETH.MESH.00584291	ETH.MESH.00584292
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584488	ETH.MESH.00584494
6/6/2006	Fournier H re New Standards for Urethral Slings	ETH.MESH.00584491	ETH.MESH.00584497
2/19/2004	Email thread re: Prolene Mesh.	Eth.Mesh.00584714	
2/19/2004	Kammerer G email chain re Prolene Mesh	ETH.MESH.00584714	ETH.MESH.00584715
4/19/2004	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT	ETH.MESH.00584811	ETH.MESH.00584813

3/10/2006	Next Generation Mesh Discussion Agenda	ETH.MESH.00585672	ETH.MESH.00585673
5/9/2006	Email re: Particle Loss on TVT	Eth.Mesh.00585802	
5/9/2006	Kammerer G email re Particle loss of TVT	ETH.MESH.00585802	ETH.MESH.00585802
6/12/2006	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)	ETH.MESH.00585842	ETH.MESH.00585843
1/20/2006	Kammerer G email chain re TVT - TVT-O specifications	ETH.MESH.00585906	ETH.MESH.00585909
2/13/2006	Kammerer G email chain re TVM discussions	ETH.MESH.00585937	ETH.MESH.00585939
3/28/2007	Performance Evaluation Technical Report	ETH.MESH.00593165	ETH.MESH.00593189
	PPT Slides “TVT Abbrevo U.S. Launch Overview.”	Eth.Mesh.00632655	
	U.S. Launch Overview	ETH.MESH.00632655	ETH.MESH.00632655
		ETH.MESH.00684368	
12/19/2005	Mahar K mail chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/19/2005	Mahar K email chain re Lazer cut mesh	ETH.MESH.00687819	ETH.MESH.00687822
12/21/2005	Honjnoski P email chain re CER - LCM	ETH.MESH.00700344	ETH.MESH.00700345
10/5/2006	Hernandez J email re TVT LCM Early EU Feedback	ETH.MESH.00746204	ETH.MESH.00746208
??/??/06	Product Pointer	ETH.MESH.00746209	ETH.MESH.00746209
	Surgeon Evaluation Questions for Laser Cut Mesh	ETH.MESH.00746210	ETH.MESH.00746212
11/9/2010	TVT Classif IFU Revision Project Design Requirements Waiver Rationale Memo	ETH.MESH.00748213	ETH.MESH.00748213
5/15/2008	Prolift +M FDA Clearance Letter	ETH.MESH.00748451	ETH.MESH.00748803
8/23/2005	Final Report, PSE Accession Number 05-0395, Project Number 67379	ETH.MESH.00749504	ETH.MESH.00749517
3/9/2006	Interim Report Test and Control ARticle Material Characterization Program	ETH.MESH.00750766	ETH.MESH.00750769
11/21/2005	Process Qualification Completion Report Version 1	ETH.MESH.00752863	ETH.MESH.00752893
	RMR - TVT-S	ETH.MESH.00752921	ETH.MESH.00752925
	Risk Management Report Revision History for RMR-0000021	ETH.MESH.00752928	ETH.MESH.00752932
	TVT Secur Harm/Hazards Table	ETH.MESH.00752933	ETH.MESH.00752934
12/17/2008	Osman R email chain re 2008 Budget Spend	ETH.MESH.00772228	ETH.MESH.00772229
12/17/2008	Osman R email chain re Updated Fair Balance for TVT Brochure	ETH.MESH.00772231	ETH.MESH.00772232
	Presentation: Gynecare TVT Secur Project Overview PLT REview	ETH.MESH.00826057	ETH.MESH.00826067
4/12/2007	Thunder Meeting Minutes	ETH.MESH.00832555	ETH.MESH.00832556
1/22/2008	Thunger Meeting Minutes	ETH.MESH.00832562	ETH.MESH.00832564
	Arnaud, Robinson presentation: Characteristics of Synthetic Materials Used in Prolapse and Incontinence Surgery	ETH.MESH.00838428	ETH.MESH.00838469
8/31/2007	Robinson D email chain re Asking TVT Complication? - Fraying	ETH.MESH.00844331	ETH.MESH.00844335
8/31/2007	Robinson D email Chain re Asking TVT Complication? - Fraying	ETH.MESH.00844341	ETH.MESH.00844344

5/27/2008	Risk Benefit Analysis TVT-S	ETH.MESH.00853802	ETH.MESH.00853806
1/22/2004	Presentation: Sales Training Launch Meeting Gynecare TVT Obturator System	ETH.MESH.00857821	ETH.MESH.00857923
	Luscombe presentation: Top Ten Reasons to Pursue Gynecare TVT Obturator System	ETH.MESH.00857891	ETH.MESH.00857893
	Internal Dan Smith memo – Gynecare board discussed risk of no clinical prior to launch, will proceed as no clinical needed	Eth.Mesh.00858080	
	Smith D Memo re Gynecare Board risk discussion before launch	ETH.MESH.00858080	ETH.MESH.00858081
06/??/03	Gynecare R&D Monthly Update - June	ETH.MESH.00858092	ETH.MESH.00858093
3/4/2003	Gynecare R&D Monthly Update - March	ETH.MESH.00858094	ETH.MESH.00858095
	Gynecare R&D Monthly Update -- May	ETH.MESH.00858096	ETH.MESH.00858097
6/3/2003	Mulberry Weekly Meeting Minutes for 06/03/2003	ETH.MESH.00858175	ETH.MESH.00858177
	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale	ETH.MESH.00858252	ETH.MESH.00858253
	Smith D Memo TVT Secur Lessons Learned Review	ETH.MESH.00858636	ETH.MESH.00858641
	Where the market is heading	ETH.MESH.00858891	ETH.MESH.00858891
6/1/2009	Smith D email chain re Sample medio TVTO	ETH.MESH.00860142	ETH.MESH.00860144
6/2/2003	Smith D email re My notes from the Thursday evening presentation 5/22/03 and Friday's surgery	ETH.MESH.00862727	ETH.MESH.00862728
2/27/2004	Email re: 2 TVT Complaints concerning allegedly brittle mesh	Eth.Mesh.00863391	Eth.Mesh.00863393
2/27/2004	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh	ETH.MESH.00863391	ETH.MESH.00863393
3/9/2004	Emails re: Complaint TVTO	Eth.Mesh.00863405	Eth.Mesh.00863407
3/9/2004	Luscombe B email chain re Complaint TVT-O	ETH.MESH.00863405	ETH.MESH.00863407
7/24/2003	Smith D email chain re TOVT developments	ETH.MESH.00864101	ETH.MESH.00864102
8/15/2001	Luscombe B email chain re Aug 11 program	ETH.MESH.00864131	ETH.MESH.00864133
5/5/2004	Smith D email chain re TVT-O	ETH.MESH.00864407	ETH.MESH.00864408
9/8/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864490	ETH.MESH.00864492
9/14/2004	Smith D email chain re Ongoing TVT-O Action Items	ETH.MESH.00864493	ETH.MESH.00864496
3/2/2004	Email re: Reminder on BLUE mesh!	Eth.Mesh.00865322	Eth.Mesh.00865323
3/2/2004	Owens C email chain re Reminder on BLUE mesh	ETH.MESH.00865322	ETH.MESH.00865323
8/14/2007	Thunder meeting minutes	ETH.MESH.00869908	ETH.MESH.00869909
		ETH.MESH.00869977	
6/2/2006	Expert Meeting Minutes - Meshes for Pelvic Floor Repair	ETH.MESH.00870466	ETH.MESH.00870476
6/6/2006	Ethicon Expert Meeting Meshes for Pelvic Floor Repair	Eth.Mesh.00870466	
8/13/2006	London Brown, A email chainre LIGHTning clinical strategy	ETH.MESH.00870481	ETH.MESH.00870482

2/8/2006	Yale M email chain re MHRA request - TVT (change to dying process)	ETH.MESH.00874032	ETH.MESH.00874035
		ETH.MESH.00876900	
1/18/2008	Zaddem V email re 510(k) mesh data	ETH.MESH.00906445	ETH.MESH.00906445
4/13/2005	Sunoco, Inc MSDS	ETH.MESH.00918015	ETH.MESH.00918019
	MSDS for Sunoco C4001 Polypropylene Homopolymer.	Eth.Mesh.00918015	
1/1/1970	St Hilaire P re Bidirectional Elasticity Statement	ETH.MESH.00922443	ETH.MESH.00922446
	Weisberg M Final Draft CER	ETH.MESH.00998286	ETH.MESH.00998291
12/13/2005	St. Hilaire email chain re Clinical Expert Report Laser Cut Mesh	ETH.MESH.00998292	ETH.MESH.00998293
6/22/2006	Gadot, Harel email re LCM - Launch Strategy EMEA	ETH.MESH.00998347	ETH.MESH.00998347
4/18/2006	Weisberg M and Robinson D CER	ETH.MESH.00998349	ETH.MESH.00998355
3/9/2007	Smith D email chain re Draft of latest "cookbook"" after Germany trip	ETH.MESH.01000323	ETH.MESH.01000329
6/4/2013	Professional Education Index	ETH.MESH.01000449	ETH.MESH.01000452
12/19/2006	Robinson D email chain re TVT-S Cookbooks	ETH.MESH.01000731	ETH.MESH.01000733
2/8/2005	Final Report Ethicon Study No S04/2-2-1 A 3 month -re-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model	ETH.MESH.01037530	ETH.MESH.01037545
	TVT and TVT-O Risk Management Report Rev. 1	Eth.Mesh.01066916	Eth.Mesh.01066932
	TVT and TVT-O RMR Rev 1	ETH.MESH.01066916	ETH.MESH.01066932
	Smith, Lond Brown presentation: Gynecare TVT Secur	ETH.MESH.01150009	ETH.MESH.01150059
		ETH.MESH.01154031	
6/6/2001	Barbolt Memo to Ciarroca re Biocompatibility Risk Assessment for the TVT-L Device	ETH.MESH.01159961	ETH.MESH.01159962
1/16/2001	Dormier D email chain re Corporate Product Characterization December Monthly Report	ETH.MESH.01160507	ETH.MESH.01160518
	Marketing Brochure - Make Data and Safety Your Choice	ETH.MESH.01186068	ETH.MESH.01186072
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny visit	ETH.MESH.01202101	ETH.MESH.01202103
1/7/2009	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit	ETH.MESH.01202101	ETH.MESH.01202103
11/14/2008	Hinoul presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203998
11/14/2008	Hinoul Austria Presentation: The future of surgical meshes: the industry's perspective	ETH.MESH.01203957	ETH.MESH.01203957
	TVT Abbrevo Risk Management Report Rev. 1	Eth.Mesh.01212090	Eth.Mesh.01212099
	TVT-Abbrevo RMR Rev 1	ETH.MESH.01212090	ETH.MESH.01212099
	Hutchinson Final Report An Exploratory 91-Day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats	ETH.MESH.01217925	ETH.MESH.01217959
	Revision History for dFMEA0000242	ETH.MESH.01218019	ETH.MESH.01218019
	TVT Laser Cut Mesh Risk Management Report Rev. 1	Eth.Mesh.01218099	Eth.Mesh.01218103

	TVT RMR Rev 1	ETH.MESH.01218099	ETH.MESH.01218103
4/5/2007	State of Knowledge in "mesh shrinkage"--What we know	Eth.Mesh.01218361	Eth.Mesh.01218367
4/5/2007	Spychaj K memo re Shrinking meshes	ETH.MESH.01218361	ETH.MESH.01218367
3/19/2003	Final Test Report - Prolene	ETH.MESH.01218446	ETH.MESH.01218449
5/9/2006	Flatow J email chair re Particle loss on TVT	ETH.MESH.01219629	ETH.MESH.01219630
3/20/2006	CPC-2006-0014, Completion Report for the Design Verification of TVT Laser Cut Mesh Particle Loss at 50%Elongation	Eth.Mesh.01219984	
3/20/2006	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh	ETH.MESH.01219984	ETH.MESH.01219994
10/14/2003	Kammerer G re Technical data on competitive meshes from Europe	ETH.MESH.01220710	ETH.MESH.01220711
5/4/2006	Kammerer G email re New Standards for Urethral Slings	ETH.MESH.01221024	ETH.MESH.01221025
3/9/2006	Kammerer G email chain re Elongation properties of LCM	ETH.MESH.01221618	ETH.MESH.01221619
3/7/2006	Weisberg, Robinson Clinical Expert Report	ETH.MESH.01221735	ETH.MESH.01221740
	Elongation Characteristics of Laser Cut Prolene Mesh for TVT	Eth.mesh.01222075	Eth.mesh.01222079
2/28/2003	Cirellli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model	ETH.MESH.01222617	ETH.MESH.01222654
	Nilsson Podcase Transcript	ETH.MESH.01228079	ETH.MESH.01228084
2/5/2008	Robinson CER Gynecare Prolift+M	ETH.MESH.01259495	ETH.MESH.01259509
6/28/2002	Lawler T email re Polypropylene Mesh	ETH.MESH.01264260	ETH.MESH.01264260
2/17/2011	Zaddem V email re mesh pore size - tissue compliance and contraction	ETH.MESH.01264497	ETH.MESH.01264498
3/14/2008	Risk Management Report (Legacy) for TVT and TVT-O	Eth.Mesh.01265223	Eth.Mesh.01265239
	RMR TVT and TVT-O Rev 1	ETH.MESH.01265223	ETH.MESH.01265239
	TVT and TVT-O Risk Management Report Rev. 2	Eth.Mesh.01268264	Eth.Mesh.01268277
	RMR for TVT and TVT-O Revision History for RMR-0000044	ETH.MESH.01268264	ETH.MESH.01268277
	TVT Laser Cut Mesh Risk Management Report Rev. 2	Eth.Mesh.01310061	Eth.Mesh.01310065
	TVT Laser Cut RMR Rev 2	ETH.MESH.01310061	ETH.MESH.01310065
	TVT Laser Cut Mesh Risk Management Report Rev. 3	Eth.Mesh.01310476	Eth.Mesh.01310481
	TVT RMR Rev 3	ETH.MESH.01310476	ETH.MESH.01310481
		ETH.MESH.01316489	
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01316727	ETH.MESH.01316765
5/14/2001	Target Sheet Design History: DH0263-DH0278	ETH.MESH.01317508	ETH.MESH.01317613
4/25/2002	DDSA Re-Evaluation for TVT	ETH.MESH.01317510	ETH.MESH.01317514
7/12/2000	TVT-2 needles Introducer Revision 8	ETH.MESH.01317515	ETH.MESH.01317524
5/14/2001	TVT-O Design History Book 2 of 7	ETH.MESH.01317769	ETH.MESH.01318358
	TVT-O Design History Book 2 of 7	Eth.Mesh.01317769	

5/14/2001	Target Sheet DH1017-DH1019(bk5)	ETH.MESH.01318359	ETH.MESH.01318831
	TVT-O Design History Book 4 of 7	Eth.Mesh.01318359	
5/14/2001	TVT-O Design History Book 6 of 7	ETH.MESH.01318832	ETH.MESH.01319499
	TVT-O Design History Book 6 of 7	Eth.Mesh.01318832	
5/14/2001	TVT-O Design History Book 7 of 7	ETH.MESH.01319500	ETH.MESH.01320123
	TVT-O Design History Book 7 of 7	Eth.Mesh.01319500	
6/18/2007	Volpe, Meier presentation: Exploratory Program "Thunder" A Material designed for pelvic floor	ETH.MESH.01405166	ETH.MESH.01405166
1/3/2009	Potential Failure Mode and Effects Analysis Chart Process FMEA	ETH.MESH.01407837	ETH.MESH.01407857
3/21/2006	Product Specification TVT-S Revision B	ETH.MESH.01410044	ETH.MESH.01410047
	Test Report No. B0086/02 Test for local effects after implantation	ETH.MESH.01424246	ETH.MESH.01424290
7/11/2001	91-day intramuscular tissue reaction study conducted in rats.	Eth.Mesh.01425079	ETH.MESH.01425113
2/27/2006	Design Validation Report TVTSDVLPRD2	ETH.MESH.01592178	ETH.MESH.01592188
	Ethicon Memo re: Prolene Pore Size	Eth.Mesh.01752532	
	Ethicon R&C Memo re Mesh design argumentation issues	ETH.MESH.01752532	ETH.MESH.01752535
	Clinical Expert Report ULTRAPRO	ETH.MESH.01760853	ETH.MESH.01760861
12/15/2006	Arnaud A email re TVT-S Cookbooks	ETH.MESH.01770534	ETH.MESH.01770534
	TVT-Secur: "Hammock" position - description for right-handed surgeon	ETH.MESH.01770535	ETH.MESH.01770540
	TVT-Secur: "U" Position - description for right-handed surgeon	ETH.MESH.01770541	ETH.MESH.01770546
12/20/2006	Robinson emai chainl re TVT-S Cookbooks	ETH.MESH.01784428	ETH.MESH.01784435
	LCM CER	Eth.mesh.01784823	Eth.mesh.01784828
1/17/2010	Hinoul, P email chain re +M relaxation	ETH.MESH.01785259	ETH.MESH.01785260
0/0/2010	Hinoul email reporting meeting with Klosterhalfen	Eth.Mesh.01785259	
8/17/2010	Clinical Expert Report TVT Abbrevo	ETH.MESH.01795909	ETH.MESH.01795929
	Abbrevo Clinical Expert Report	Eth.Mesh.01795909	
	Draft Smith presentation: The Mesh Story	ETH.MESH.01805985	ETH.MESH.01806002
4/25/2002	Test Report - Prolene	ETH.MESH.01808729	ETH.MESH.01808741
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices	ETH.MESH.01809080	ETH.MESH.01809081
12/14/2004	Leibowitz B Memo re Comparison of Laser-Cut and Machine-Cut TVT Mesh to Meshes from Competitive Devices (BE-2004-1641)	ETH.MESH.01809080	ETH.MESH.01809081
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12/10/2004	Bell S email chain re VOC on Laser cut mesh	ETH.MESH.01811770	ETH.MESH.01811772
6/20/2003	Elbert K email chain re Design Control	ETH.MESH.01814371	ETH.MESH.01814372
	Work Instruction for New Product Design Control	ETH.MESH.01814384	ETH.MESH.01814400

8/17/2004	Burns J email chain re TVT-O Dr. Feagins case follow up	ETH.MESH.01815505	ETH.MESH.01815513
6/17/2003	Smith D email chain re Discussion 11th June 2003	ETH.MESH.01815611	ETH.MESH.01815613
	Spreadhseet mesh characeristis	ETH.MESH.01816988	ETH.MESH.01816989
5/9/2006	Mesh Development Timeline	Eth.Mesh.01816990	
??/??/06	Mesh development timeline	ETH.MESH.01816990	ETH.MESH.01816990
7/31/2007	Thunder Meeting minutes	ETH.MESH.01819505	ETH.MESH.01819506
7/5/2009	Robinson Literature Review - Pelvic Organ Prolapse Repair Procedures	ETH.MESH.01819528	ETH.MESH.01819572
10/18/2006	Smith D email chain re TVT-Secur	ETH.MESH.01822361	ETH.MESH.01822363
3/25/2004	Zaddem V email chain re disclosure questions	ETH.MESH.01988643	ETH.MESH.01988644
	Test Method Applicability/Suitability Rev History for FM-0000020	ETH.MESH.01992234	ETH.MESH.01992237
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02010834	ETH.MESH.02010855
12/2/2004	Rousseau R email re umbilical hernia surgery sales contacts	ETH.MESH.02011199	ETH.MESH.02011199
2/23/2007	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure	ETH.MESH.02017152	ETH.MESH.02017158
03/??/01	Hellhammer B Meshes in Pelvic Floor Repair Findings from literature reivew and interviews with surgeons	ETH.MESH.02017169	ETH.MESH.02017190
		ETH.MESH.02017169	
	Biocompatability of Prosima components final draft insert into 510k	ETH.MESH.02020023	ETH.MESH.02020024
4/13/2005	Sunco C4001 Polypropylene Homopolymer MSDS	ETH.MESH.02026591	ETH.MESH.02026595
??/??/03	Marketing brochure Gynemesh PS A New Mesh for Pelvic Floor Repair Early Clinical Experience	ETH.MESH.02053629	ETH.MESH.02053632
		ETH.MESH.02053629	
5/21/2009	Protocol Study Title: A Phase 2 Study to Evaluate the Safety ad Efficiary of the Fibrin Pad Hemostatic Dressing in Trauma Patients Undergoing Re-Laprotomy after Initial Damages Control Surgery	ETH.MESH.02059212	ETH.MESH.02059232
6/22/2001	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes	ETH.MESH.02089392	ETH.MESH.02089399
8/8/2006	Holste Barbolt Mesh chara sign page	ETH.MESH.02091873	ETH.MESH.02091873
	Physician Post-Operative Questionnaire	ETH.MESH.02106803	ETH.MESH.02106803
6/18/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.02126222	ETH.MESH.02126227
10/6/2008	Barbolt, T. Mechanisms of Cytotoxicity for TVT Polypropylene	Eth.Mesh.02134271	
	Memo to Rippy re Mechanisms of Cytotoxicity for TVT Polypropylene Mesh	ETH.MESH.02134271	ETH.MESH.02134273
5/26/2000	Corporate Product Characterization Product Safety Profile for PROLENE Mesh	Eth.Mesh.02134274	
5/26/2000	Product Safety Profile	ETH.MESH.02134274	ETH.MESH.02134279

12/5/2003	Biocompatibility Risk Assessment for the Gynecare TVT	Eth.Mesh.02134312	
12/5/2003	Memo re Biocompatibility Risk Assessment for the Gynecare TVT Obturator	ETH.MESH.02134312	ETH.MESH.02134314
	TVT Secur System Design Validation Report	ETH.MESH.02135955	ETH.MESH.02135968
4/22/2009	Holste J email chain re Question on Moncryl absorption	ETH.MESH.02148431	ETH.MESH.02148432
06/??/09	Intermediate Report - Prolapse Mesh Explants 6/2009	ETH.MESH.02157879	ETH.MESH.02157880
3/26/2008	Robinson D email chain re UP	ETH.MESH.02170708	ETH.MESH.02170709
6/24/2003	Toddywala R email re Project Mulberry	ETH.MESH.02180737	ETH.MESH.02180737
3/29/2004	Memo from Jean de Leval, MD	Eth.Mesh.02180759	
3/29/2004	de Leval J memo	ETH.MESH.02180759	ETH.MESH.02180761
11/12/2004	Email re: Mesh Fraying: Dr. EBERHARD Fraying: DR. EBERHARD letter	Eth.Mesh.02180826	Eth.Mesh.02180827
11/12/2004	Menneret D email chain re Mesh Fraying: Dr. Eberhard letter	ETH.MESH.02180826	ETH.MESH.02180827
11/10/2004	Sibylle B Memo to Menneret D re TVT blue	ETH.MESH.02180828	ETH.MESH.02180830
10/18/2004	Translation of PD Doctor Eberhard's letter	ETH.MESH.02180833	ETH.MESH.02180833
4/22/2003	Burkley D email chain re Pore size request	ETH.MESH.02183533	ETH.MESH.02183536
4/3/2009	Rathore O email chain re Analytical characterization - Optimization of STructure	ETH.MESH.02184435	ETH.MESH.02184436
4/27/2010	Flint J email chain re surface area	ETH.MESH.02185004	ETH.MESH.02185004
2/16/2011	Biomechanical consideration for Pelvic floor mesh design	ETH.MESH.02185584	ETH.MESH.02185605
10/16/2007	Arnold, K email chain re LIghtning - Mesh Strength Design Requirement	ETH.MESH.02195798	ETH.MESH.02195799
2/5/2008	Robinson CER Gynecare Prolift +M	ETH.MESH.02198933	ETH.MESH.02198947
6/10/2008	Batke B email chain re Bisphenol A (BPA) - Question	ETH.MESH.02207388	ETH.MESH.02207389
	Spreadsheet re Mesh characteristics	ETH.MESH.02212840	ETH.MESH.02212842
08/??/10	Presentation: TOPA & SCION PA Alignment	ETH.MESH.02218268	ETH.MESH.02218292
	Presentation Script	ETH.MESH.02219162	ETH.MESH.02219164
	Rule 26 Expert Report of Howard Jordi, PhD in Carolyn Lewis case	ETH.MESH.02219202	ETH.MESH.02220048
	Meshes/Devices Chart	ETH.MESH.02227368	ETH.MESH.02227368
	Meshes/Devices	ETH.MESH.02227368	ETH.MESH.02227368
1/13/2011	TVT-O Marketing video	ETH.MESH.02229061	ETH.MESH.02229061
	Abbrevo marketing video	Eth.Mesh.02229061	
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2/3/2003	Burkley D email chain re Athos: Analytical Testing	ETH.MESH.02268613	ETH.MESH.02268614
2/21/2003	Dion, D email re Prolene additives and exposure	ETH.MESH.02268618	ETH.MESH.02268618
1/23/2003	Prolene Resin Manufacturing Specifications Letter	Eth.Mesh.02268619	ETH.MESH.02268621

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2/26/2004	Samon J email chain re mesh implants - user needs	ETH.MESH.02270823	ETH.MESH.02270825
		ETH.MESH.02283781	
1/13/2005	O'Bryan S email chain re IFU Prolift	ETH.MESH.02286052	ETH.MESH.02286053
	Spreadsheet re matrix new material - improved mesh characteristics	ETH.MESH.02310498	ETH.MESH.02310498
	Landgreve S, Smith D, Trzewik J,Matrix - A powerful new tool in "Advanced Tissue Reconstruction:	ETH.MESH.02310501	ETH.MESH.02310501
10/21/2008	Pompilio S email re Information about FDA notification on use of mesh in pelvic surgery	ETH.MESH.02310653	ETH.MESH.02310657
	PPT Presentation titled "Tissue Reaction and Integration of Polypropylene-Based Surgical Mesh in Rats" by R.W. Hutchinson and Thomas Barbolt	ETH.MESH.02319001	
08/??/01	TVT IFU	ETH.MESH.02340306	ETH.MESH.02340369
	TVT IFU	ETH.MESH.02340331	ETH.MESH.02340335
2/11/2005	TVT IFU	ETH.MESH.02340471	ETH.MESH.02340503
10/13/2008	TVT IFU	ETH.MESH.02340504	ETH.MESH.02340567
12/16/2005	TVT-S IFU	ETH.MESH.02340568	ETH.MESH.02340755
3/7/2005	TVT-O IFU 03/07/20050-005/19-2005	ETH.MESH.02340756	ETH.MESH.02340828
	TVT-O IFU (3/7/2005-5/19/2005)	Eth.Mesh.02340756	
1/7/2004	TVT-O IFU (1/7/2004-3/4/2005)	ETH.MESH.02340829	ETH.MESH.02340901
	TVT-O IFU (1/7/2004-3/4/2005)	Eth.Mesh.02340829	
5/12/2010	TVT-O IFU (05/12/2012-present)	ETH.MESH.02340902	ETH.MESH.02340973
	TVT-O IFU (5/12/2010-present)	Eth.Mesh.02340902	
5/25/2005	TVT-O IFU (05/25/2005-04/29/2008)	ETH.MESH.02340974	ETH.MESH.02341046
	TVT-O IFU (5/25/2005-4/29/2008)	Eth.Mesh.02340974	
4/23/2008	TVT-O IFU (04/23/2008-05/07/2010)	ETH.MESH.02341047	ETH.MESH.02341118
	TVT-O IFU (4/23/2008-5/7/2010)	Eth.Mesh.02341047	
	Prosima IFU	ETH.MESH.02341407	ETH.MESH.02341410
4/23/2013	IFU Index and Production Bates Range Chart	ETH.MESH.02341954	ETH.MESH.02341954
4/25/2013	IFU Index	ETH.MESH.02342194	ETH.MESH.02342194
	No mesh is the best . . .	ETH.MESH.02588170	ETH.MESH.02588180
	Trzewik, Meier presentation: Exploratory Program "Thunder" A new material designed for pelvic floor	ETH.MESH.02588182	ETH.MESH.02588193
12/14/2010	ERM team meeting minutes	ETH.MESH.02588977	ETH.MESH.02588978
5/18/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.02589032	ETH.MESH.02589079
11/24/2010	TVT Abbrevo PPT Presentation.	Eth.Mesh.02596794	
11/24/2010	TVT Abbrevo Dublin Meeting brochure	ETH.MESH.02596794	ETH.MESH.02596794
		ETH.MESH.02612883	
	Ultrasonic Slitting of PROLENE Mesh for TVT Feasibility Study	ETH.MESH.02614396	ETH.MESH.02614517

1/3/2012	Prosima 510(k) clearance letter	ETH.MESH.02658539	ETH.MESH.02658542
6/16/2008	Design Requirements Matrix Prolift+M /Lightning	ETH.MESH.02915783	ETH.MESH.02915797
	Study Notes	ETH.MESH.02992136	ETH.MESH.02992137
	Judi Gauld presentation: Evidence to Support Innovation	ETH.MESH.02995494	ETH.MESH.02995500
8/25/2008	Draft - Presentation: T-Pro (Thunder) Pipeline Leadership Team (PLT) Stage Gate: Discovery Initiation	ETH.MESH.03021946	ETH.MESH.03021970
	Presentation: FDA REview R&D	ETH.MESH.03032928	ETH.MESH.03032944
2/16/2011	Holste email chain re Prosima +M clin strat	ETH.MESH.03146492	ETH.MESH.03146493
8/12/2007	Project plan Prosima M project lightning	ETH.MESH.03294572	ETH.MESH.03294581
5/1/2006	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)	ETH.MESH.03358217	ETH.MESH.03358224
3/6/2006	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR	ETH.MESH.03358398	ETH.MESH.03358402
		ETH.MESH.03360387	
3/16/2004	Smith D email chain re TVTO training Carmel Ramage	ETH.MESH.03364540	ETH.MESH.03364544
??/??/09	TVT IFU	ETH.MESH.03427878	ETH.MESH.03427946
	Chart of pain associated with TVT-O.	Eth.Mesh.03454726	
10/12/2005	Holloway ltt Ethicon France re fraying	ETH.MESH.03535750	ETH.MESH.03535750
11/22/2005	Process Qualification Completion Report	ETH.MESH.03648795	ETH.MESH.03648810
	Revision History for FM-0000167	ETH.MESH.03652924	ETH.MESH.03652955
	Table re Raw data for force to achieve elongation	ETH.MESH.03658980	ETH.MESH.03658980
9/10/2009	Ng W email chain re August 2009 YTD Travel & Consulting spend	ETH.MESH.03699545	ETH.MESH.03699546
	Weisberg Clinical Expert Report Gynecare TVT Secur System	ETH.MESH.03714599	ETH.MESH.03714614
10/14/2011	Polypropylene Mesh for Pelvic Floor Repair - Focus on Mesh Exposure Road to Improvement - Bailhe	ETH.MESH.03719177	ETH.MESH.03719195
3/12/2012	Smith D email chain re tape position at rest	ETH.MESH.03731339	ETH.MESH.03731340
	Revision History (PR602-003)	ETH.MESH.03742571	ETH.MESH.03742597
5/10/2013	Bentley G email chain re Production of Policy before design 30(b)(6) deposition	ETH.MESH.03742864	ETH.MESH.03742865
	PA Consulting	ETH.MESH.03750903	ETH.MESH.03750950
	Spreadsheet product characteristics	ETH.MESH.03751168	ETH.MESH.03751175
	Table comparing meshes	ETH.MESH.03751168	ETH.MESH.03751168
5/18/2010	TVT Abbrevo Launch Planning Stage Gate PLT brochure	ETH.MESH.03753682	ETH.MESH.03753682
	Abbrevo Launch PPT Wanted to meet unmet demand of less persistent pain with Obturator	Eth.Mesh.03753682	
8/8/2003	Email re: Transient Leg Pain with MULBERRY	Eth.Mesh.03803462	
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6/6/2001	Emails re TVT recommendation from Dr. Alex Wang	Eth.Mesh.03905472	
6/6/2001	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang	ETH.MESH.03905472	ETH.MESH.03905472
9/18/2005	Weisberg M email chain re clinical expert report	ETH.MESH.03905619	ETH.MESH.03905621
10/14/2002	"Confidential - Trans-Obturator TVT - Procedure In-Out" by Axel Arnaud	Eth.Mesh.03907327	Eth.Mesh.03907330
10/17/2002	Arnaud Memo "Confidential Trans-Obturator TVT-Procedure In-Out"	ETH.MESH.03907327	ETH.MESH.03907330
5/1/2002	Document titled: "Second Generation TVT" by Axel Arnaud	Eth.Mesh.03907468	
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6/6/2003	LeTreguilly L email chain re TVT Serious complication	ETH.MESH.03907853	ETH.MESH.03907854
4/27/2005	Evans P email re Prolene v Polypropylene	ETH.MESH.03908707	ETH.MESH.03908708
8/21/2000	ARnaud A email chain re Pelvic floor repair Procedural Strategy	ETH.MESH.03909708	ETH.MESH.03909713
10/13/2002	Email re: Soft Prolene	Eth.Mesh.03910183	ETH.MESH.03910193
10/13/2002	Arnaud email chain re Soft Prolene	ETH.MESH.03910183	ETH.MESH.03910185
11/26/2002	Arnaud A email chain re Mini TVT - mesh adjustment	ETH.MESH.03910418	ETH.MESH.03910421
7/21/2004	Arnaud A email chain re TVT Erosion	ETH.MESH.03910799	ETH.MESH.03910800
5/25/2003	Arnaud A email re Follow up Mulberry	ETH.MESH.03910890	ETH.MESH.03910892
2/20/2003	Email re: TVT complications (an Prof. Hausler)	Eth.Mesh.03911107	Eth.Mesh.03911108
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8/14/2003	Arnaud A email chain re Transient Leg Pain with Mulberry	ETH.MESH.03911390	ETH.MESH.03911394
1/31/2006	Email re: TVT-TVT-O Specifications	Eth.Mesh.03911712	
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1/8/2007	Arnaud A eail re TVT Cookbooks	ETH.MESH.03912639	ETH.MESH.03912639
	Draft re TVT-S IFU	ETH.MESH.03912647	ETH.MESH.03912651
4/14/2005	Toddywala, R email chain re Ultrapro	ETH.MESH.03915567	ETH.MESH.03915572
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11/28/1999	Bianchi R email chain re TVT event	ETH.MESH.03917309	ETH.MESH.03917312
10/18/2002	Email re Gynemesh	ETH.MESH.03918067	ETH.MESH.03918068
3/26/2003	Arnaud A email re Mulberry	ETH.MESH.03919404	ETH.MESH.03919405
12/19/2006	Robinson D email chain re TVT Secur	ETH.MESH.03921499	ETH.MESH.03921500

12/5/2006	Smith D email chain re TVT-SECUR follow up on conference call	ETH.MESH.03921580	ETH.MESH.03921583
11/30/2006	Gotter R email re The more procedures the more problems	ETH.MESH.03921612	ETH.MESH.03921612
10/3/2007	Beveridge A email re AMS mini Arc	ETH.MESH.03922261	ETH.MESH.03922261
6/6/2007	Beveridge A email chain re TVT Secure & Nice	ETH.MESH.03922405	ETH.MESH.03922406
1/16/2007	Robinson D email chain re TVT Secur procedural steps	ETH.MESH.03922950	ETH.MESH.03922951
1/16/2007	Buchon X email chain re French data on TVT Secur	ETH.MESH.03922953	ETH.MESH.03922953
1/10/2007	Robinson D email chain re Report from Austria	ETH.MESH.03922966	ETH.MESH.03922967
6/6/2000	Hellhammer B - Meshes in Pelvic Floor Repair Findings from literature review and conversations/interviews with surgeons	ETH.MESH.03924557	ETH.MESH.03924586
		ETH.MESH.03924557	
	Meeting Notes	ETH.MESH.03926030	ETH.MESH.03926031
1/16/2007	"Confidential: History of TVT-O" by Axel Arnaud	Eth.Mesh.03932909	Eth.Mesh.03932911
	History of TVT-O	ETH.MESH.03932909	ETH.MESH.03932911
	The history of TVT	ETH.MESH.03932912	ETH.MESH.03932914
2/20/2006	Buchon X email chain re Pr Cosson	ETH.MESH.03938897	ETH.MESH.03938898
4/3/2012	deLeval J email re Alerte TVT Abbrevo	ETH.MESH.03941617	ETH.MESH.03941618
4/3/2012	Hinoul P email chain re Alerte TVT Abbrevo	ETH.MESH.03941621	ETH.MESH.03941622
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3/1/2012	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation	ETH.MESH.04015102	ETH.MESH.04015104
4/13/2005	Holste, J email chain re Ultrapro	ETH.MESH.04020134	ETH.MESH.04020137
1/13/2005	Report - Analysis of Competitors meshes: Dynamesh, Dynamesh Light, Dynamesh IPOM	ETH.MESH.04036976	ETH.MESH.04036981
	Innovations in Mesh Development Boris Batke	ETH.MESH.04037600	ETH.MESH.04037600
2/29/2012	Jamiolkowski D email chair re Your Professional Opinion	ETH.MESH.04038180	ETH.MESH.04038181
10/??/00	TVT Update Success & Complications - Bernard Jacquetin	ETH.MESH.04044797	ETH.MESH.04044800
6/18/2008	Carl G. Nilsson Interview	ETH.MESH.04048515	ETH.MESH.04048520
6/25/2008	KOL Interview: Carl G. Nilsson	ETH.MESH.04048515	ETH.MESH.04048515
05/26/????	Michele Meschia Presentation: The evolution of slings for SUI	ETH.MESH.04058175	ETH.MESH.04058209
	5/26-27 PPT Presentation titled "The Evolution of Slings for SUI."	Eth.Mesh.04058175	
8/4/2009	Fujihara M email re SUI & PFR New Competitor Identified in Brazil	ETH.MESH.04066979	ETH.MESH.04066980
2/2/2009	Meeting Agenda "AE and complication of the lsings	ETH.MESH.04081189	ETH.MESH.04081190
2/9/2009	Meeting Agenda by Meng Chen re "AE and complication of the slings"	Eth.Mesh.04081189	Eth.Mesh.04081190
1/29/2009	Email re: TVT IFUs on tape extrusion, exposure and erosions	Eth.Mesh.04093125	

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1/9/2007	Gadot H email chain re Report from Austria	ETH.MESH.04204341	ETH.MESH.04204342
12/??/06	Womens Health - Monthly Report December 06	ETH.MESH.04204343	ETH.MESH.04204343
	PDP Design Control Revision History for PR800-011	ETH.MESH.04316544	ETH.MESH.04316562
3/21/2006	Process Specificagtion Gynecare TVT Secure	ETH.MESH.04385192	ETH.MESH.04385197
7/19/1996	Product Safety Profile - Prolene	ETH.MESH.04447134	ETH.MESH.04447142
3/5/2012	CDMA Meeting Minutes - 2012	ETH.MESH.04548236	ETH.MESH.04548242
3/20/2012	Hinoul P email chain re Polypropylene Mesh	ETH.MESH.04937874	ETH.MESH.04937876
4/2/2012	Hinoul P email chain re Prof de Leval - TVT Abbrevo	ETH.MESH.04938298	ETH.MESH.04938299
2/28/2006	Corporate Product Characterization Plan for Gynecare TVT-S	ETH.MESH.04939027	ETH.MESH.04939035
7/18/2005	Corporate Product Characterization Plan for Gynecare TVT S	ETH.MESH.04939148	ETH.MESH.04939157
7/16/2010	Holste, Jophnson Memo to Leslie Young re Preclinical Efficacy Assessment for Ethicon Gynecare Gynemesh	ETH.MESH.04940233	ETH.MESH.04940233
	Holste presentation: Lightweight Mesh Developments	ETH.MESH.04941016	ETH.MESH.04941049
4/18/2005	Klosterhalfen B email re Ultrapro vs Prolene Soft Mesh	ETH.MESH.04945496	ETH.MESH.04945496
2/3/2012	Email thread re: A few things.	Eth.Mesh.05107016	
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	Spreadsheet of Ethicon product positioning for various products.	Eth.Mesh.05109369	
	Spreadsheet re product positioning	ETH.MESH.05109369	ETH.MESH.05109398
1/20/2010	Holste email chain re Tissue reaction ULTRAPRO	ETH.MESH.05127423	ETH.MESH.05127430
11/7/2005	Patire-Singer W email chain re TVT Records	ETH.MESH.05220458	ETH.MESH.05220464
4/7/2006	TVT IFU	ETH.MESH.05222673	ETH.MESH.05222705
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	Eth.Mesh.05224295	
7/1/2010	TVT Abbrevo 510(k) Clearance and Application	ETH.MESH.05224295	ETH.MESH.05224391
9/8/2000	TVT-IFU	ETH.MESH.05225354	ETH.MESH.05225385
	TVT IFU	ETH.MESH.05225380	ETH.MESH.05225384
	Meier presentation: Mesh Properties - How important are they?	ETH.MESH.05237872	ETH.MESH.05237910
4/8/2009	Hinoul email chain re Tensile Properties of POP Mesh	ETH.MESH.05238373	ETH.MESH.05238374
4/9/2009	Jones, S email re Tensile Properties of POP Mesh	ETH.MESH.05238382	ETH.MESH.05238384
	Article on pp change in sheep model	ETH.MESH.05240144	ETH.MESH.05240144
	Presentation Wissenschaftliche Grundlagen adn klinsche Evidenz von Netz-Implantaten	ETH.MESH.05243697	ETH.MESH.05243704
12/21/2004	Holste email chain re TVT Next generation Questions	ETH.MESH.05245392	ETH.MESH.05245397
1/3/2006	Smith D email chain re REsults of TVTx prelinical trial	ETH.MESH.05246116	ETH.MESH.05246122

3/10/2005	Next Generation Mesh Discussion - Agenda	ETH.MESH.05246527	ETH.MESH.05246528
6/16/1999	28-day intramuscular tissue reaction study of TVT Mesh conducted in rats.	Eth.Mesh.05315240	ETH.MESH.05215295
1/8/2014	Deposition Subject Matter table	ETH.MESH.05315240	ETH.MESH.05315279
11/7/2002	Lab Notebook Histology Processing and Tissue Inventory Record	ETH.MESH.05316755	ETH.MESH.05316755
11/6/2011	Miller D email chain re Prolift professional education	ETH.MESH.05337217	ETH.MESH.05337220
	Operating Procedure for Failure Modes and Effects Analsis	ETH.MESH.05432198	ETH.MESH.05432224
	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes	ETH.MESH.05442973	ETH.MESH.05442975
	Operating Procedure for Optical Evaluation to Determine Porosity of Mesh Samples Using the Nikon Stereomicroscope and Image-Pro Plus Image Analysis System	ETH.MESH.05443059	ETH.MESH.05443064
	Temocin - Pore Size Measurement of Surgical Mesh Products	ETH.MESH.05443077	ETH.MESH.05443085
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	SEM Images for Ten Year PROLENE Study	Eth.Mesh.05453719	ETH,MESH.05453727
10/15/1992	Seven Year Data for Ten Year Prolene Study	ETH.MESH.05453719	ETH.MESH.05453727
8/1/2006	Trzweik J email chain re Fotos cadevar lab	ETH.MESH.05454207	ETH.MESH.05454214
1/18/2003	Ethicon Surgeon Panel Meeting Agenda, Notes	ETH.MESH.05455878	ETH.MESH.05455898
??/??/06	2006 Johnson Medal Nomination Ultrapro Loghtweight mesh product line	ETH.MESH.05457602	ETH.MESH.05457609
8/20/2012	Vellucci, ltr re Ethicon ceases to commenrcialize prosima	ETH.MESH.05467804	ETH.MESH.05467804
4/13/2005	Barbolt, T email chain re Ultrapro	ETH.MESH.05469908	ETH.MESH.05469912
11/??/08	Batke presentation: Ultrapro Plug Tokyo	ETH.MESH.05478745	ETH.MESH.05478780
10/??/03	Lightweight Mesh Value Proposition	ETH.MESH.05479410	ETH.MESH.05479410
11/10/2004	Presentation by Boris Batke (Ethicon R&D): The (clinical) argument of lightweight mesh in abdominal surgery	Eth.Mesh.05479411	
11/10/2004	PPT Presentation by Boris Batke: “The (Clinical Argument of Lightweight Mesh in Abdominal Surgery.”	Eth.Mesh.05479411	
11/10/2004	Presentation by Boris Batke: The (clinical) argument of lightweight mesh in abdominal surgery	ETH.MESH.05479411	ETH.MESH.05479411
	TVT and TVT-O RMR Rev 2	ETH.MESH.05479411	ETH.MESH.05479424
5/30/2011	Spreadsheet listing microporous, medium and macroporous meshes	Eth.Mesh.05479535	

	Product Spreadsheet	ETH.MESH.05479535	ETH.MESH.05479535
3/1/2011	Presentation: ETHICON Polypropylene Mesh Technology	Eth.Mesh.05479717	
03/??/11	Boris Batke presentation: ETHICON Polypropylene Mesh Technology	ETH.MESH.05479717	ETH.MESH.05479717
10/2/2003	Ultrapro Mesh Pricing Committee Presentation	ETH.MESH.05483362	ETH.MESH.05483362
12/1/2007	Sponsored Research Contract The Curators of the University of Missouri	ETH.MESH.05489861	ETH.MESH.05489867
	Scientific Sgtatement Helhammer, Kohler, Holste, Shrinking Meshes?	ETH.MESH.05495419	ETH.MESH.05495422
2/27/2006	Design Requirements Matrix	ETH.MESH.05502894	ETH.MESH.05502928
	Clinical Infection Risk Assessment for Bynecare TVT Universal	ETH.MESH.05505944	ETH.MESH.05505946
12/19/2006	Smith D email chain re TVT-S Cookbooks	ETH.MESH.05519476	ETH.MESH.05519481
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11/1/2004	Smith D email chain re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
11/1/2004	Smith D email re Update from Oct 27 cadaver lab	ETH.MESH.05548122	ETH.MESH.05548123
4/29/2005	Komamycky P email chain re Bio compatibility samples	ETH.MESH.05549096	ETH.MESH.05549100
3/11/2005	Holste J email chain re Infection resk implantation TVT U	ETH.MESH.05549189	ETH.MESH.05549191
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		eth.mesh.05642725	
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5/8/2011	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair	ETH.MESH.05701011	ETH.MESH.05701058
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	Boris Batke Presentation: Chronic Pain Prevention/future--Bioengineer's point of view	ETH.MESH.05916450	ETH.MESH.05916450
	Presentation: Solving the Device Design Puzzle	ETH.MESH.05918082	ETH.MESH.05918116
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	Performance Evaluation Technical Report	Eth.mesh.06696367	Eth.mesh.06696379
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8/27/2008	CE Mark Technical File PMH-2008-01	ETH.MESH.06851860	ETH.MESH.06852464
	Presentation: TVT Obturator System	ETH.MESH.06856958	ETH.MESH.06856981
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6/22/2011	Investigating Mesh Erosion in Pelvic Repair	ETH.MESH.07192929	ETH.MESH.07192929
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10/15/1992	Seven Year Data for Ten Year PROLENE Study (and SEM images)	Eth.Mesh.07690752	ETH.MESH.07690788
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8/10/1990	Five Year Report re Ten Year In Vivo Suture Study	ETH.MESH.11336474	ETH.MESH.11336487
	Risk Assessment Summary for Products in the Gynecare TVT Secur System - Revision Hx for 100146510	ETH.MESH.11353422	ETH.MESH.11353439
12/??/10	TVT Abbrevo Patient Brochure	ETH.MESH.11434264	ETH.MESH.11434272
1/1/2011	TVT Abbrevo Selling Guide	ETH.MESH.11434367	ETH.MESH.11434379
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8/10/1990	Ten Year In Vivo Suture Study - Five Year Report	ETH.MESH.12729337	ETH.MESH.12729350
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11/12/1987	Prolene Explants Study Meeting Minutes.	Eth.Mesh.12831407	ETH.MESH.12831408
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	MSDS for Dilauralthiodipropionate (DLTDP)	N/A	
	MSDS for Santonox R	N/A	
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